

THE DEVELOPMENT AND EVALUATION OF A NOVEL PASSIVE APPROACH TO MAINTAINING RESIDUUM VOLUME IN TRANS-TIBIAL AMPUTEES

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Table of glossary

Item	Definition
Air Pneumatic Suspension System	A system comprising a series of air bladder, control circuit board (including a pressure sensor and microcontroller), pump, and valve.
Magnetic-lock system	A prosthetic suspension system consisting of a dermo liner with distal cap and magnetic lock
Suction Socket Suspension System	A socket with one-way expulsion valve and urethane sleeve, or seal-In liner suspension to keep the socket sealed.
Silicone liners	Roll-on socket/liner made from silicon or other suitable material
Seal-In liner	A liner with seal/s.
Shuttle-lock system	A prosthetic suspension system consisting of a dermo liner with distal pin and shuttle lock
Vacuum-Assisted Suspension System	A suspension system comprising a vacuum pump which draws the air between the liner and socket through its exhaust, and a urethane sleeve suspension.

Table of abbreviations

Word / Phrase	Abbreviation
3-Dimentional	3D
Air Pneumatic Suspension System	APSS
Anatomical Coordinate System	ACS
Body Weight	BW
Calibrated Anatomical System Technique	CAST
Coefficient of Variance	CV
Computerised Tomography	CT
Confidence Interval	CI
Coordinate 3D	C3D

Double Limb Support	DLS
Global Coordinate System	GCS
Ground Reaction Forces	GRFs
Intra-class Correlation Coefficient	ICC
Instrumented Trans-tibial Prosthesis	ITTP
Magnetic Resonance Imaging	MRI
Minimal Detectable Differences	MDD
Motion Capture Units	MCUs
National Health Service	NHS
Participant	Pt
Patellar Tendon Bearing	PTB
Patellar Tendon Bearing Supra-Condylar	PTB-SC
Pressure	P
Principle Investigator	PI
Prosthetics and Orthotics	P&O
Quality of Life	QoL
Residuum Volume Fluctuations	RVFs
Range of Motion	RoM
Suction Socket Suspension System	SSSS
Single Limb Support	SLS
Standard deviation	SD
Standard Error of Measurements	SEM
Statistical Package for Social Sciences	SPSS
Technical Coordinate System	TCS
Total Surface Bearing Socket	TSB Socket
Un-Loaded	UL
University of Salford	UoS
Vacuum-Assisted Suspension System	VASS
Visual 3D	V3D

Abstract

Reduction in residuum volume during periods of upright mobility is a common problem in lower limb amputees. A vacuum pump to reduce the in-socket air pressure has been shown to conserve residuum volume, but is expensive and not widely available. In this thesis an alternative (passive) approach to reducing pressures within the socket during gait is proposed, based on building in a distal void into the socket, thereby exploiting Boyles' Law. The aims of this thesis were to: 1) develop a test prosthesis, allowing for testing of passive, modified passive, and active systems and, 2) compare the performance of these systems in terms of residuum volume changes, comfort, and gait kinematics and ground reaction forces.

For the first aim, an Instrumented Trans-tibial Prosthesis (ITTP) was developed. The socket was designed with a configurable distal void and could also be used in conjunction with a commercially available pump.

For the second aim and prior to conducting the main study, the repeatability of a laser-based scanner system to measure residuum volume, as well as gait measures, were evaluated in five trans-tibial amputee subjects. The methods proved to be highly repeatable.

In the main study, five trans-tibial amputee participants were cast and fitted with bespoke ITTP. Residuum volume was measured before and after walking across 3 test-conditions (passive – conventional; passive plus distal void; and active). Participants were asked to rest for 20 minutes between test-conditions to allow the residuum volume to return to steady-state. Gait kinematics and GRFs were collected during the walking trials and comfort assessed after each set of trials. Following resting, the residuum volume decreased, relative to the baseline volume, by 4.2% for the conventional passive system and less than 2% for both the passive plus distal void and active system. The results suggest the proposed approach shows promise and further work is merited.

Chapter 1: Introduction

Lower limb prostheses should be functional, comfortable, and have acceptable cosmetic appearance. A number of different problems may arise while walking with a prosthesis. One common problem is a gradual reduction in residuum volume experienced by many amputees over the course of a day. The mechanisms causing this are poorly understood, but believed to include intrinsic factors, such as disruption or absence of key physiological elements, or muscle atrophy, as well as extrinsic factors, such as the in-socket air pressure. A reduction in residuum volume can lead to pistoning, the distal/proximal displacement of the residuum relative to the socket. Pistoning may have associated with various unwanted features, such as gait asymmetry and pain, leading to reduced satisfaction on the part of the user. This thesis focuses on a novel approach to the maintenance of residuum volume.

Different methods, commonly including adding extra sock/s or an extra liner, are used to manage the short-term reduction in residuum volume during walking. However, adding socks or another liner may increase the pressure on the residuum, making the problem worse. Doffing the prosthesis to allow the residuum volume to recover is also used, but clearly is far from ideal.

A number of small studies suggest that vacuum-based suspension systems help to maintain residuum volume, through creating a low in-socket air pressure. These suspension systems can be categorised as: 1) Passive system (Suction Socket Suspension System (SSSS)) and; 2) Active system (Vacuum-Assisted Suspension System (VASS)), which use a pump, such as the Limb-Logic Communicator¹. The former is easier to use, more cosmetic, and lighter weight, compared to the latter.

Only three studies have compared the SSSS and VASS (1-3). They reported that VASS are better than SSSS in terms of maintaining the residuum volume. However, the VASS is not always the best option. For example, there are prosthesis users who do not like, or cannot tolerate the constant low in-socket pressure. Further, VASS systems are expensive, special training is required to fit the system, and they

¹<https://www.willowwoodco.com/products-services/elevated-vacuum/limblogic-communicator/>

are not available for all prosthesis users. This thesis explores an alternative passive approach to the maintenance of residuum volume based on the introduction of a void in the socket. By creating a relatively large air pocket within the socket, it is hypothesised that in-socket fluctuations in air pressure during gait may be reduced. This in turn may impact on residuum volume maintenance.

Therefore, the main aims of the thesis were to:

1. Design and build a test prosthesis that allow participants to be tested while walking with a SSSS, a modified SSSS and a VASS.
2. Use the new prosthesis to compare the performance of the SSSS, modified SSSS, and VASS in terms of:
 - Maintenance of residuum volume;
 - Comfort and;
 - Gait kinematics and Ground Reaction Forces (GRFs).

The rest of this thesis is separated into six chapters. **Chapter 2** introduces the background to this thesis. It begins by describing lower limb loss, its levels, causes, prevalence and incidence and its impact on amputees' quality of life. This is followed by a review of common lower limb prosthetic components, including suspension systems and socket designs. Following on from this, pistoning is defined, its potential causes and impacts on lower limb amputees. Common methods for characterising pistoning are reported, together with an overview of the reported magnitudes of pistoning, and their effects on gait. As the maintenance of residuum volume is the focus for this thesis, methods to maintain residuum volume over time are described. This section begins with techniques to measure residuum volume, followed by the underlying causes of short term changes in residuum volume and how these are managed using passive methods. The active systems for residuum volume management are introduced, and their limitations discussed. Finally, the aims and objectives of the study are presented.

To address the study aims an Instrumented Trans-tibial Prosthesis (ITTP) was developed (**Chapter 3**). The calculations informing the key feature of the design, the volume of the distal void in the socket, are presented. Based on the design volume,

a configurable design of the ITTP is presented, together with associated geometry of components.

In **Chapter 4**, a repeatability study is presented. The aims of this study were to assess the within-day repeatability of residuum volume measurement and gait parameters in a group of traumatic trans-tibial amputees. The methods used are described, including recruitment, measurement systems used, and data collection protocols. The residuum volume and gait kinematics are presented. Finally, the chapter finishes with a discussion and conclusions.

The protocol for the main study, the focus for which was a comparison between the SSSS, modified SSSS, and VASS, was piloted as explained in **Chapter 5**. This was carried out to identify different problems that may arise while collecting the data and enable any changes to the main study protocol. One participant with unilateral trans-tibial amputation level was recruited for this purpose. The results are presented and issues that were identified were addressed for the protocol of the main study. Finally, the amended study protocol is presented.

The main study is reported in **Chapter 6**. The aims of this study were to first; build a test prosthesis that allow participants to be tested walking with a SSSS, a modified SSSS, and a VASS and, second; use the new prosthesis to compare the performance of the SSSS, modified SSSS, and VASS in terms of maintenance of residuum volume, comfort and, gait kinematics and GRFs. Results are presented from five trans-tibial amputees fitted with the ITTP (defined in Chapter 3). The results are presented and finally, the discussion then conclusions are drawn.

The final chapter presents an overview of the entire thesis, highlights its limitations and novelty, and suggests future work (**Chapter 7**).

Chapter 2: Literature review

2.1. Introduction

This chapter begins by describing lower limb absence, its levels, causes, prevalence and incidence, and its impact on the quality of life of amputees. As this thesis focuses on trans-tibial amputees, a brief overview of prostheses for this population is introduced, including suspension systems and socket designs. This is followed by a definition of pistoning, possible causes and its impacts on lower limb amputees. Methods for the measurement of pistoning are introduced and critically appraised. The section concludes with an overview of the reported magnitudes of pistoning and the influences of pistoning on gait.

The primary focus for this thesis, management of the residuum volume, is discussed in the second part of this chapter. This section begins by describing residuum volume measurement techniques, which is followed by the possible causes of short-term Residuum Volume Fluctuations (RVFs) and a brief review of passive methods for managing the short-term reduction in residuum volume. The section is concluded with a discussion of active methods, which typically employ a pump to reduce the in-socket air pressure acting on the residuum. Finally, the scientific rationale, aims and objectives of the study are presented.

2.2. Lower limb absence and amputation

2.2.1. Introduction

Limb absence may be due to congenital factors or amputation (4, 5).

Figure 2.1 shows the different levels of lower limb amputation.

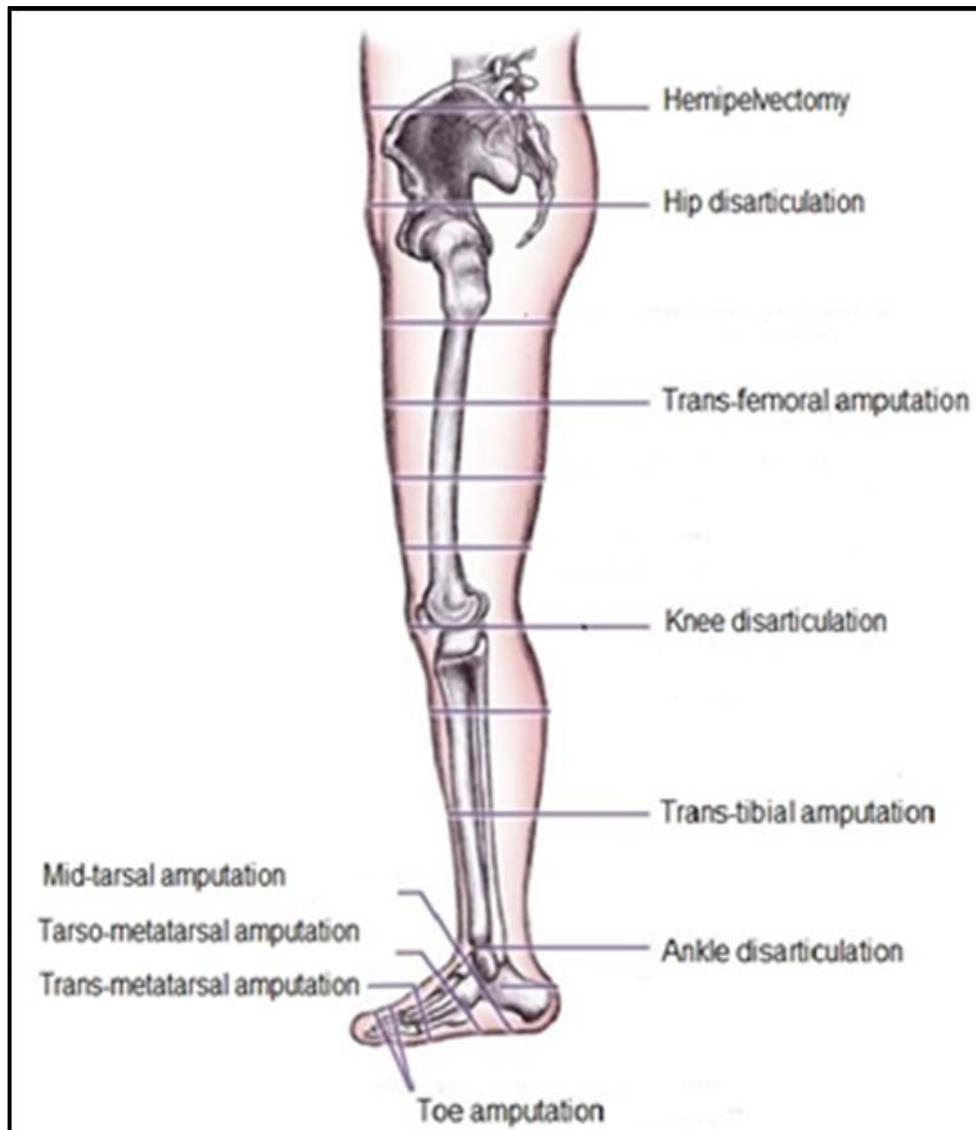


Figure 2.1: Levels of the lower limb amputation (6).

2.2.2. Causes, incidence of amputation and prevalence of amputees

The common reasons for lower limb absence include peripheral vascular disease (PVD), trauma, malignant tumours, severe infection, neurological disorders and congenital (7-9).

Table 2.1 illustrates the causes and incidence of lower limb amputation in the UK (9).

Table 2.1: Causes and incidence of lower limb amputation in the UK, based on the UK limbless statistics 2010 - 2011 (9).

Cause	Number of amputees	Percentage %
Trauma	457	8.36
Vascular	3124	57.12
Infection	471	8.61
Neurological disorder	79	1.45
Tumour	116	2.12
Congenital	174	3.18
No data	1048	19.16
Total	4569	100

Bain et al (2016) (10) reported that the number of diabetic patients in the UK is rising, mainly amongst the young (10). This rise is associated with obesity and reduced levels of activity (10). In another study, Ziegler-Graham et al. (2008) reported that 1.6 million people were living with limb loss in the USA in 2005, and this figure is expected to rise to 3.6 million by the year 2050 (11). In the UK, vascular amputees make up more than half (57%) of lower limb amputees, as shown in *Table 2.1*.

Table 2.2 illustrates the prevalence of lower limb amputees due to vascular disease with comorbidity of diabetes, showing the scale of the clinical challenge.

Table 2.2: Prevalence of lower limb amputees due to vascular disease with comorbidity of diabetes in different countries (11, 12).

Country	Period	Prevalence (Per 100,000)
United Kingdom	1997-2000	285
Andalusia	2004-2006	344
Germany	2005-2007	253
Sweden	1997-2006	197
United States	2005	571

According to the UK limbless statistics 2010 - 2011 (9), the total number of lower and upper limb amputees who had been referred for prosthetic treatment to different centres in the UK during 2010 – 2011 was 5988. Of these, 5469 (91.47%) were referred with lower limb amputation (9).

Table 2.3 summarises the number of lower limb referrals in the UK by limb loss level.

Table 2.3: Number and ratio of the UK lower limb referred amputees with different levels for prosthetic treatment (9).

Amputation level	Number of amputees	% of total
Hemipelvectomy	9	0.16
Hip disarticulation	177	3.23
Trans-femoral	2041	37.32
Knee disarticulation	146	2.7
Trans-tibial	2941	53.77
Ankle disarticulation	34	0.62
Partial foot	90	1.64
Foot digits	17	0.31
Congenital limb deficiency	14	0.25
Total	5469	100%

As shown in *Table 2.3*, trans-tibial amputees make up more than half (54%) of lower limb amputees.

The impact of lower limb amputation on the quality of life

Studies comparing the Quality of Life (QoL) of lower limb amputees with healthy subjects have been carried out in order to provide an indication of the extent and causes of the problems faced (13, 14). A number of different factors are reported to affect the QoL of prosthesis users (15). Of these, amputees consistently rate pain or discomfort as being of primary importance (15). Pain or discomfort may arise from post-operative complications, such as skin infections, or may be present over the longer term. Commonly reported problems include phantom limb pain (15, 16), pain

at the residuum due to rubbing, back pain, and sound limb pain (17-19). Other physical issues such as the reduction in walking ability also impact on QoL (15).

2.3. Lower limb prostheses

2.3.1. Introduction

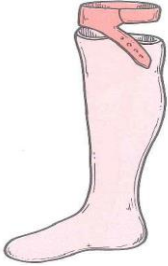

Lower limb amputees may be able to restore a degree of locomotion ability using a prosthesis. As this thesis is focused on the effects of in-socket conditions on residuum volume, this section will focus on prosthetic suspension systems and socket designs.




Suspension systems

A suspension system is used to keep the prosthesis attached to the residuum and is designed to limit residuum motion inside the socket, sometimes termed pistoning (20, 21). A number of studies have been conducted to evaluate trans-tibial suspension systems (1, 2, 21-35).

Table 2.4 and *Table 2.5* illustrate the most commonly used trans-tibial prosthetic suspension systems, together with their presumed mechanism of action and notes on their relative advantages and disadvantages. These suspension systems are grouped into: a) non vacuum-based suspension systems (Supra-condylar strap, Patellar Tendon Bearing Supra-Condylar (PTB-SC), suspension sleeve, thigh corset with side steels, shuttle-lock system, magnetic-lock system, and Air Pneumatic Suspension System (APSS)) and b) vacuum-based suspension systems (Passive System (Suction Socket Suspension System (SSSS)) and Active System (Vacuum-Assisted Suspension System (VASS)).

Table 2.4: Non vacuum-based trans-tibial prosthetic suspension systems (21, 23, 24, 31, 32, 36-39).

Suspension type		How it works	Advantages	Disadvantages
Supra-condylar strap/cuff		This suspension system comprises a leather /webbing strap with buckle or Velcro fastening which attaches above the femoral condyles (36).	<ul style="list-style-type: none"> • Simple to use • Adjustable tensioning and sizing 	<ul style="list-style-type: none"> • Not durable • Low tech design
Patellar Tendon Bearing Supra-Condylar (PTB-SC) Socket		This suspension system primarily relies on the geometry of the socket for its function. The socket extends medio-laterally and contours over the femoral condyles. A polyurethane (soft) liner is an option with this type of suspension(37).	<ul style="list-style-type: none"> • Donning and doffing is usually quick as the suspension is integrated within the socket • Enhanced Medio-lateral stability due to the high wedges • Durable compared to other suspension systems 	<ul style="list-style-type: none"> • Poor cosmesis (bulges visible through clothing) • Possible discomfort above condyles • Not suitable for amputees with residuum volume fluctuations

<p>Suspension Sleeve</p> 	<p>This suspension system comprises an elasticated sleeve which is rolled onto the proximal aspect of the socket, and the lower thigh. Skin-sleeve and sleeve-socket friction acts to resist the weight and inertial forces (37).</p>	<ul style="list-style-type: none"> • Cosmetically appealing, as the socket brim is covered • Light weight 	<ul style="list-style-type: none"> • Not durable • Increases sweating • Restricts knee flexion
<p>Thigh corset with side steels</p> 	<p>This suspension system comprises a leather corset which fastens over the affected thigh. Connection to the socket is achieved with side steels and external knee hinges (36).</p>	<ul style="list-style-type: none"> • Excellent medio-lateral stability due to the side steels • Suitable for very short residuum (i.e., very short lever arm) 	<ul style="list-style-type: none"> • May be associated with muscle atrophy • Non-cosmetically appealing (bulky) • Very low tech • Heavy
<p>Shuttle-Lock system</p> 	<p>A dermo-liner with distal pin and shuttle lock (31)</p>	<ul style="list-style-type: none"> • Reduces pistoning compared to suspension sleeve (23, 32), , PTB-SC and Supra-condylar strap (24) 	<ul style="list-style-type: none"> • Increases sweating/temperature of residuum due to the dermo-liner • Stretches the tissues at the distal end of residuum during the swing phase (39)





<p>Magnetic-Lock system</p> 	<p>A dermo-liner with distal cap and magnetic lock (31)</p>	<ul style="list-style-type: none"> • Reduces pistoning compared to shuttle-lock system (21) • Donning and doffing are more straightforward than SSSS and shuttle-lock system (31) 	<ul style="list-style-type: none"> • Increases sweating/temperature of residuum due to the dermo-liner
<p>Air Pneumatic Suspension System (APSS)</p> 	<p>A system comprising a series of air bladder, control circuit board (including a pressure sensor and microcontroller), pump, and valve (38).</p>	<ul style="list-style-type: none"> • Adapts to residuum volume fluctuations (38) • Better pressure distribution at the residuum-socket interface compared to SSSS and shuttle-lock system (38) 	<ul style="list-style-type: none"> • High cost compared to other non-vacuum based suspension systems • Training and experience are required for the prosthetists to fit this type

Table 2.5: Vacuum-based trans-tibial prosthetic suspension systems (1-3, 24, 25, 29, 31, 33).

Suspension type	How it works	Advantages	Disadvantages
<p>Suction Socket Suspension System (SSSS) (Passive System)</p> 	<p>This suspension system comprises a seal-In liner and a manual expulsion valve to evacuate the socket (31). A urethane suspension sleeve is rolled onto the proximal aspect of the socket and the lower thigh in order to form an airtight seal at the top of the socket, preventing air from entering or leaving.</p>	<ul style="list-style-type: none"> • Reduces the fluctuations in residuum volume commonly seen during walking (1-3) • Reduces pistoning compared to the shuttle-lock (25, 29, 31, 33) and magnetic-lock systems (31), as well as PTB-SC and Supra-condylar strap (24) 	<ul style="list-style-type: none"> • Increases sweating/temperature of residuum due to the seal-in liner

<p>Vacuum-Assisted Suspension System (VASS) (Active System)</p>		<p>This system comprises a dermo-liner, a urethane sleeve, and an electrical vacuum pump located on the distal aspect of the socket (1, 2). Alternatively, a manual vacuum pump can be used (3, 29). The high frictional properties of the sleeve reduce the tendency for the socket to move relative to the sleeve. In addition, the sleeve tends to form an airtight seal at the top of the socket, preventing air from entering or leaving. A vacuum pump draws out the air in between the liner and socket, creating a partial vacuum and assisting the sleeve to adhere to the socket.</p>	<ul style="list-style-type: none"> • Reduces the fluctuations in residuum volume compared to SSSS (1-3) • Reduces pistoning compared to the shuttle-lock system (29) 	<ul style="list-style-type: none"> • High cost compared to the passive systems • Training and experience are required for the prosthetists to fit this type
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With regard to the studies cited in the tables above, the quality of some of them is open to criticism. For example, 7 out of the 12 papers involved a single case study(1, 22-27) and the largest of the studies included only 19 participants (40). One study failed to report key participant statistics, including body mass (32) and another paper did not present any objective results (41). Other papers attributed surprisingly small differences in results to the differences in suspension systems (21, 25, 31). These limitations make generalisation of the results difficult and suggest further work is needed.

2.3.2. Socket designs

The suspension systems reviewed in the previous sections are used in conjunction with sockets, the design of which is reviewed here.

1. Patellar Tendon Bearing (PTB) Socket

The PTB socket has been used since 1957 (42) (*See Figure 2.2*). The socket is designed to support the majority of load through the patellar tendon bar (42). This socket design is used in conjunction with a number of different suspension systems, such as supra-condylar strap, suspension sleeve, and thigh corset with side steels.

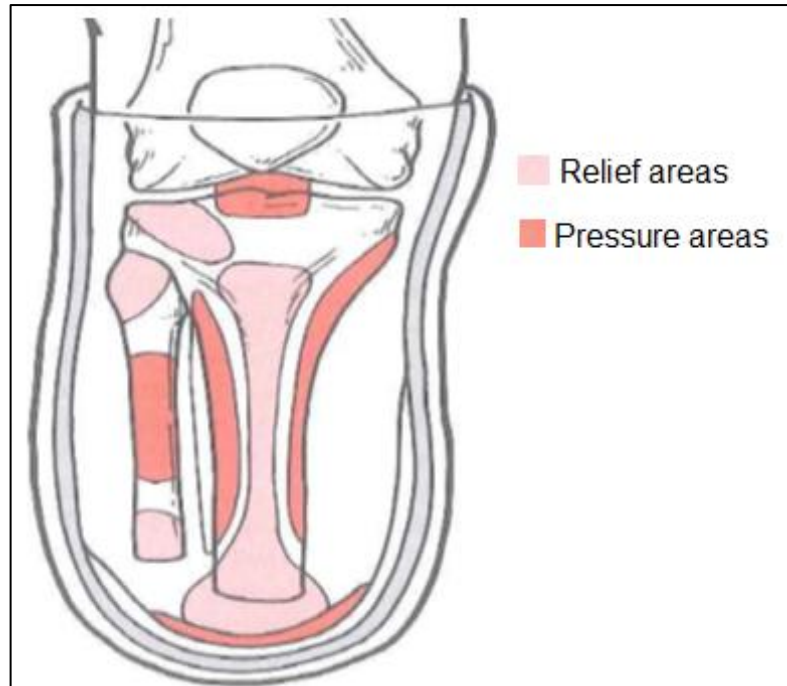


Figure 2.2: PTB socket with residuum (Anterior view) (36). It is designed with pressure areas over the muscle and relief areas over the bony prominences. However, the majority of load is designed to be taken by the patellar tendon bar and popliteal fossa area with a view to reducing the pressure acting on low tolerance areas, such as the fibular head and distal end of tibia.

2. Total Surface Bearing (TSB) Socket

The TSB socket is one of the most commonly used socket. It is designed to distribute the load over the whole residuum area (43) (See *Figure 2.3 (B)*). This socket design can be used with the SSSS, VASS (1, 2), magnetic-lock, and shuttle-lock systems.

Yigiter et al (2002) compared gait and pistoning in a study of 20 amputees using PTB and TSB sockets (43). The results showed that the TSB socket was better than the PTB socket in terms of increasing walking cadence and speed (43). In another study, 32 amputees were fitted with TSB sockets with dermo-liners after they had used a PTB socket (44). Data about the two socket designs were collected through a questionnaire. 75% of the participants preferred the TSB socket to the PTB socket (44).

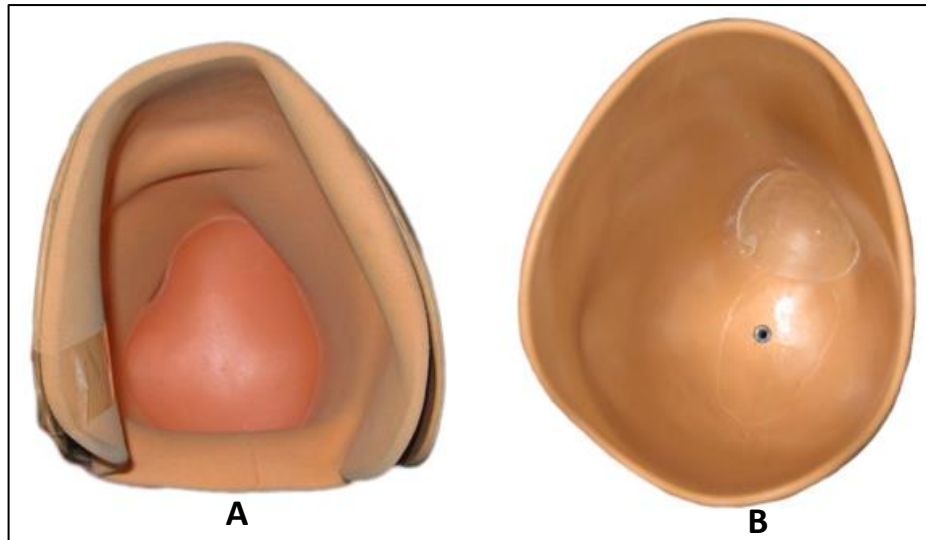


Figure 2.3: PTB socket (A) and TSB socket (B), (Top view). The latter is designed to distribute the load over the whole residuum area.

2.4. Pistoning

2.4.1. Introduction

Pistoning is the term for a commonly encountered problem which occurs during amputee gait, the small movements of the residuum relative to the socket (45-47). Pistoning results from forces acting on a compliant residuum-socket interface. During the swing phase, the gravitational and centrifugal forces act to put the socket under tensile load (37). Ground Reaction Forces (GRFs) put the socket under compressive loads during the stance phase (37). Several factors affect the compliance of the socket, including the type of the prosthetic suspension system (31, 35) and geometric fit between sockets and residuum (48). Poor socket fit may be a result of either socket manufacturing errors (48), or changes to the residuum volume over time (2, 3, 49, 50), the focus for this thesis.

One of the most important problems associated with pistoning is pain (46). Pain may arise from the repetitive shear loading of tissues and/or compressive loading of the distal end of the residuum during the stance phase of gait. Longer term, skin damage and/or infection or wound healing failure may result over time (51). Tissue damage is of particular concern for vascular amputees. Pistoning may also be associated

with embarrassing sounds when air is expelled from the socket during the stance phase of gait (31). Distal end congestion of the residuum may occur as a result of pistoning when using the shuttle-lock system (31). These effects may, in turn, be associated with poor levels of satisfaction with their prosthesis and poor function (46, 52).

2.4.2. Pistoning – loading conditions and techniques for measuring associated displacements

Pistoning in lower limb prosthetic sockets has been defined in the literature as the distal/proximal displacement of the residuum relative to the socket (34). Pistoning has typically been assessed under static loading, with loads/loading conditions selected to mimic the loads acting during gait. By convention, the loading conditions used correspond to Single Limb Support (SLS), Double Limb Support (DLS), Un-Loaded (UL), and 30N/60N/90N tensile force, intended to represent the loads seen during the swing phase (*Figure 2.4*) (34, 53). However, this approach does not account for the additional dynamic loads at heel strike and push-off. In another studies, a tilting board angled at 15° was used to mimic the loading direction seen at heel-strike (*Figure 2.6*) (24). Narita et al (1997) (32) assessed pistoning under two static conditions, SLS and 50N tensile force (*Figure 2.5*). Two other studies have assessed movement at the residuum-socket interface in sitting: in one study a movable chair and fixed foot-plate were used to apply partial (50%) and full body weight (*Figure 2.7 (A)*). (40). In another study, a shoulder harness (*Figure 2.7 (B)*) was used to apply compressive forces of 44.5N and 178N (22).



Figure 2.4: Loading cases: Left – SLS; middle - UL; and right – 30N tensile load (35).

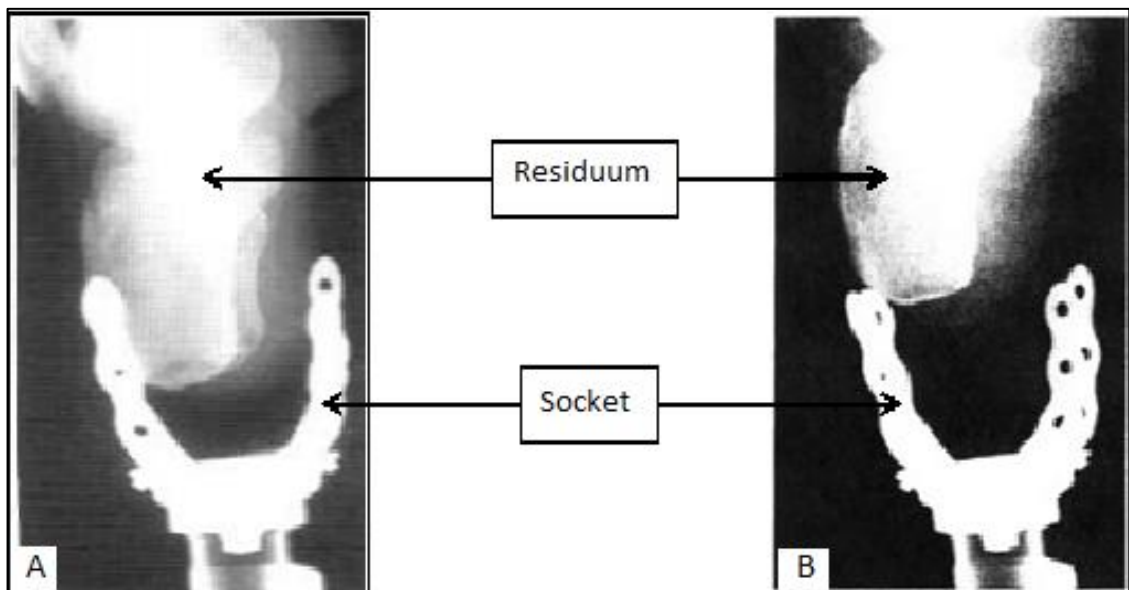


Figure 2.5: Using X-ray to assess pistoning in trans-tibial prosthetic socket under static conditions (Compression (SLS) (A) and tension (50N) (B)).

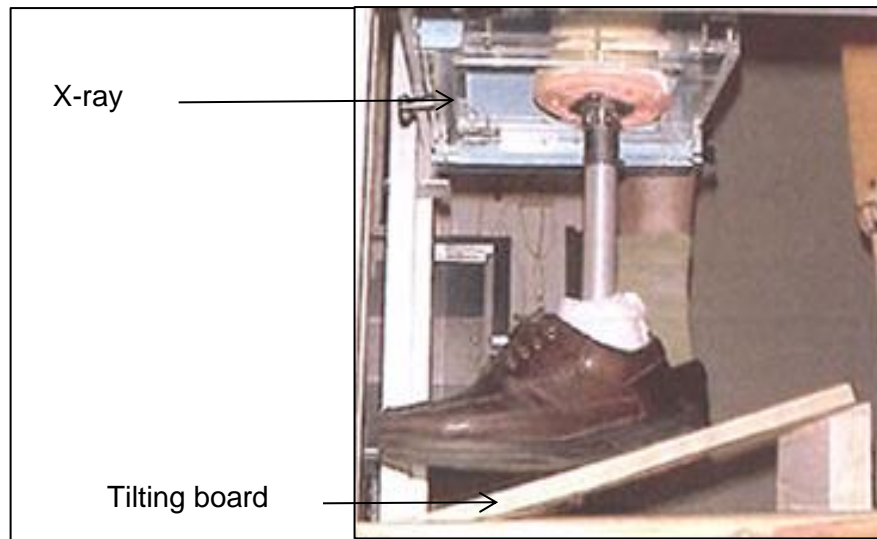


Figure 2.6: Tilting board angled at 15° was used to mimic the loading direction seen at heel-strike (24).

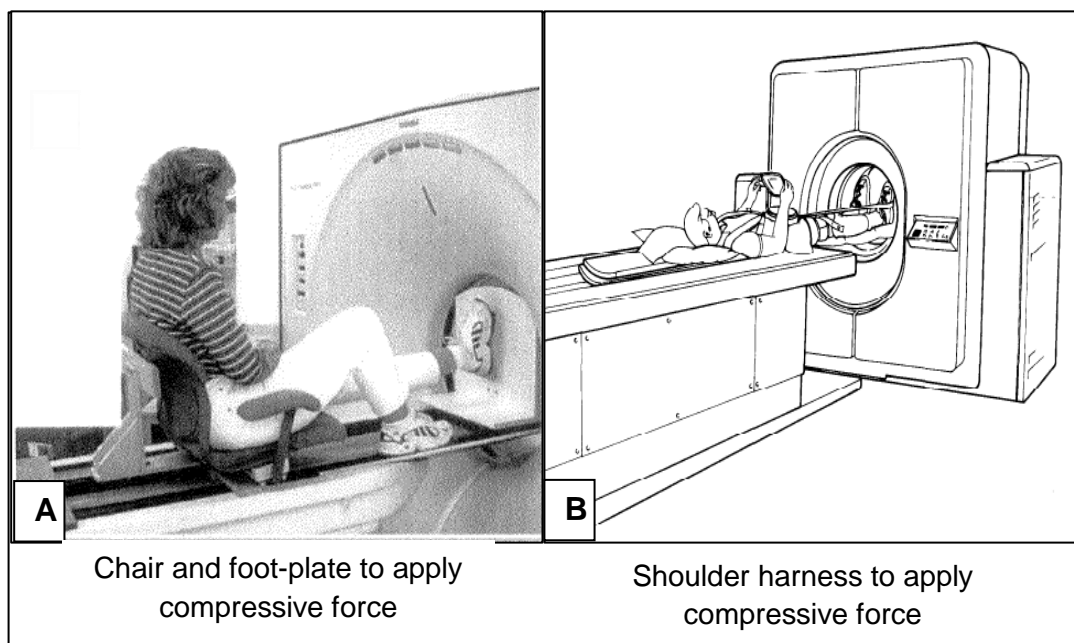


Figure 2.7: Using Computerised Tomography (CT) system to assess pistoning in trans-tibial prosthetic socket in a seated position (Applying compressive force) (22, 40).

The following sections review the methods which have been used to assess the displacements at the socket-residuum interface.

1. Methods used to assess pistoning under static loading conditions

X-ray imaging and a CT system have both been used to assess prosthetic socket fit (*Figure 2.7*) (22, 40). Images were taken under different static loading conditions (2, 23, 24, 32, 51) (*Figure 2.5* and *Figure 2.6*). The amount of pistoning was considered as the displacement of the residuum/liner relative to the socket shown in the captured images (2, 23, 24, 32, 51). However, these approaches are less than ideal, involving ionising radiation.

Gholizadeh et al (2011) (34) introduced a photographic method for the assessment of pistoning, defined in this study to be the liner-socket displacement. One line was drawn horizontally on the lateral side of the liner and another on the socket and pistoning assessed visually, using a ruler marked on the socket for calibration (*Figure 2.8 (A)*). (34). Pirouzi et al (2014) (38) drew a series of equally spaced horizontal lines on the posterior aspect of the liner, allowing for visual estimation of the movement of the posterior edge of the socket relative to the liner (38) (*Figure 2.8 (B)*). In another study, Yigiter et al (2002) (43) compared the effects of two trans-tibial socket designs on pistoning. Pistoning was assessed by marking the level of the anterior-superior brim of each socket on the residuum socks at each loading condition. The displacement relative to no load was measured using a measuring tape (43).

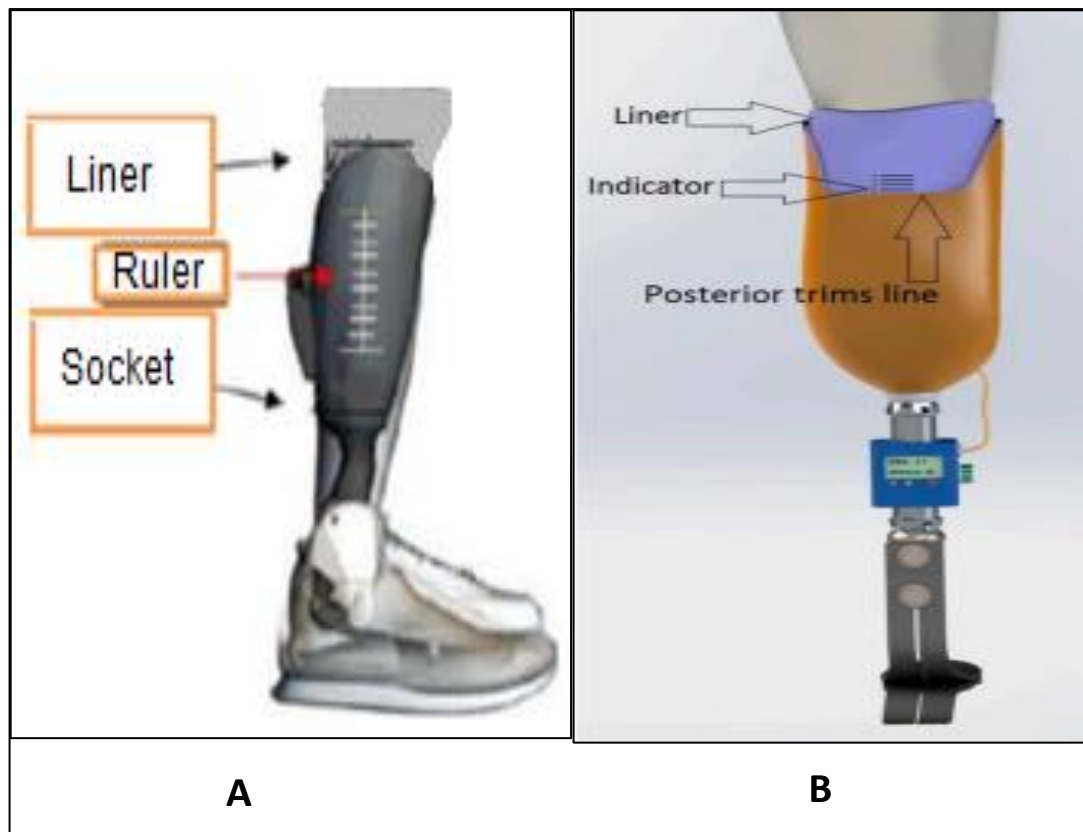


Figure 2.8: Photographic methods to assess pistoning in trans-tibial sockets under static loading conditions ((34, 38).

More recently, an optical motion capture system was used to evaluate pistoning in trans-tibial sockets (30, 31). Two spherical-reflective markers were attached to a transparent prosthetic socket and two paper-reflective markers to the liner. The relative displacement of the socket and liner under different static loading conditions were calculated from marker position data recorded by infra-red cameras (30, 31) (Figure 2.9).

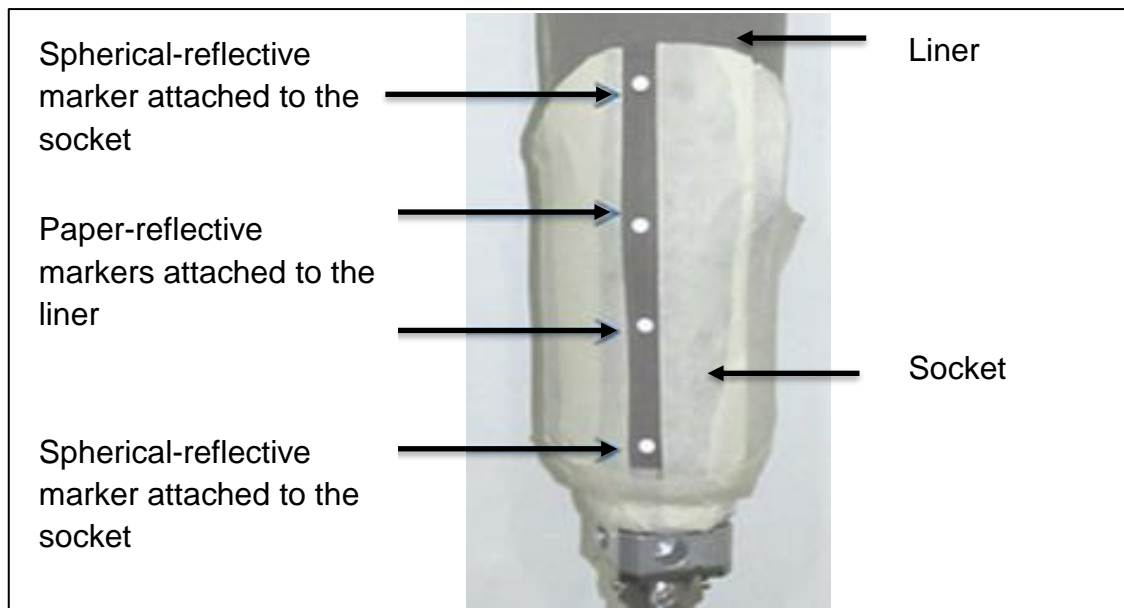


Figure 2.9: Pistoning assessment using optical motion capture system (30). *Two spherical-reflective markers were attached to a transparent prosthetic socket and two paper-reflective markers to the liner. The transparent material used for fabricating the socket would enable the cameras to detect the paper markers under the socket. The relative movement between the socket and liner-mounted markers would reflect the amount of pistoning.*

2. Methods used to assess pistoning during gait

Only a small number of studies have measured pistoning during walking. Eshraghi et al (2014) (21) used an optical motion capture system to measure pistoning during the gait of trans-tibial amputees. The system they applied in their previous study to assess pistoning under static loading conditions was used (Eshraghi et al (2012) (31)) (Figure 2.9).

In another study, a noncontact photoelectric sensor was placed at the bottom of the socket (26). The distance between the end of the residuum and the bottom of the socket was measured through light captured by the sensor (26). Video-fluoroscopy was also used to construct a video representation of movement of the residuum relative to the socket (27, 32, 41). Pistoning was considered as the vertical displacement of the residuum relative to the socket (27, 32, 41). Last of all, Wirta et

al (1990) (28) used a linear potentiometer to assess pistoning. Pistoning was considered as the axial movement of the residuum relative to the socket (28).

2.4.3. The magnitude of pistoning and impact of pistoning on gait kinematics and GRFs

A number of studies have been conducted to measure the magnitude of pistoning in lower limb prostheses (2, 31, 34). In general, studies have reported on the relationships between loads (compressive and tensile forces) and pistoning for a variety of suspension system types, including shuttle-lock, SSSS, magnetic-lock, VASS, and APSS. As can be seen in *Figure 2.10*, the magnitude of pistoning is, by convention reported relative to a zero-value corresponding to the highest compressive load. Pistoning generally increases, but in a non-linear fashion, as the loading moves from compression through to tension. It is worth noting that the studies represented in the figure used different suspension system types and methods of pistoning assessment (54).

Figure 2.10 shows the amount of residuum displacement under different loads and using various types of suspension system in trans-tibial sockets.

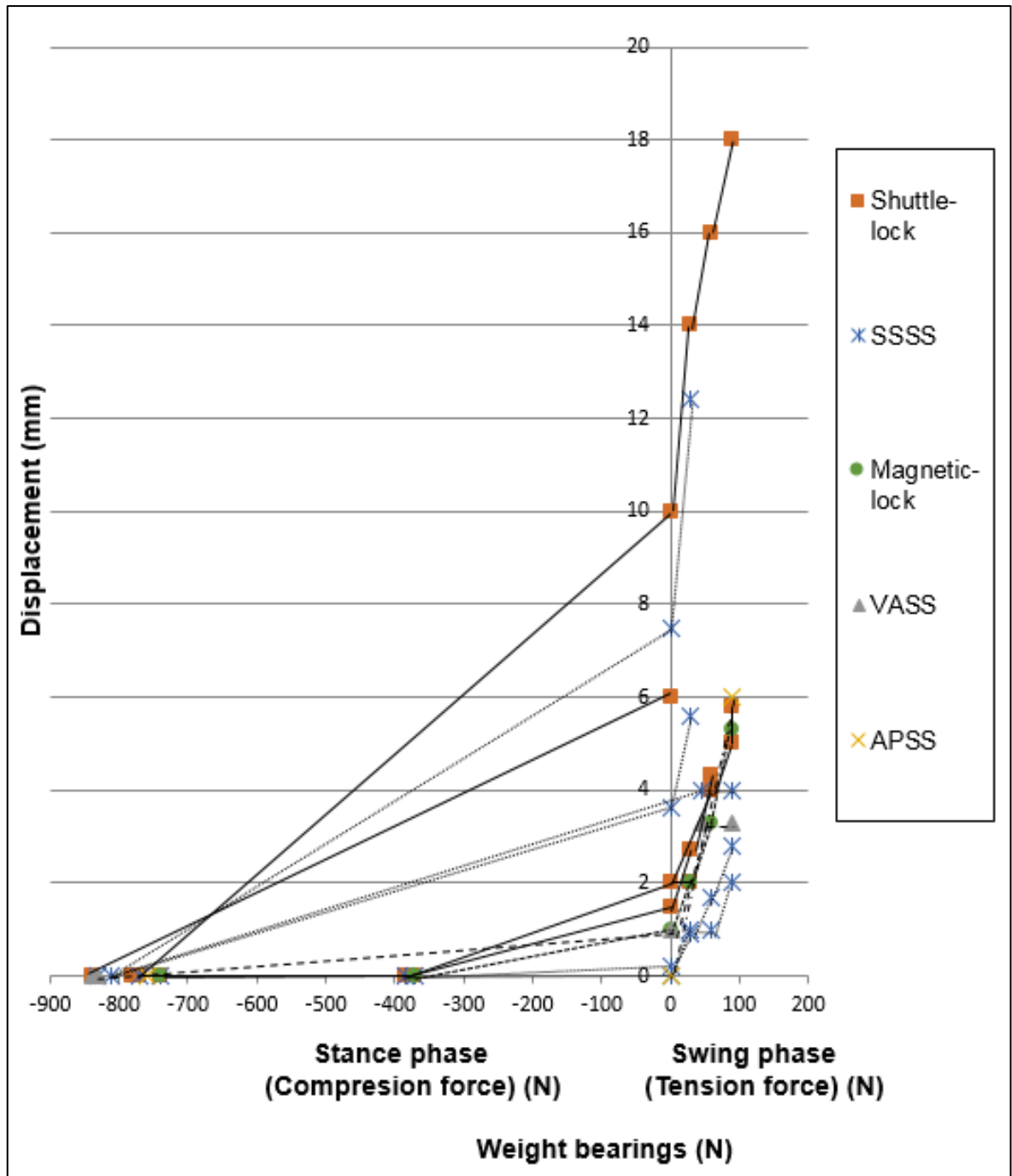


Figure 2.10: Effects of applied loads and suspension system type on the magnitude of pistoning with 5 different suspension systems: shuttle-lock (29-31, 34), SSSS (2, 30, 31, 35), magnetic-lock (31), VASS (2, 29), and APSS (38). By convention, the displacement associated with maximum compressive force (i.e., SLS) onto the prosthetic limb is reported as baseline value and distal movement of the socket relative to the proximal anatomy is considered positive.

In a recent study, Eshraghi et al (2014) (21) assessed pistoning in trans-tibial prosthetic sockets during gait, using different suspension systems. They reported a range of pistoning between 0 and 5.1 mm, across all the suspension systems. The pistoning during the swing phase was 2 mm, 3.3 mm, and 4.9 mm for the SSSS, magnetic-lock, and shuttle-lock suspension systems respectively (21). In the same paper, it was reported that the amount of pistoning during one complete gait cycle was ~4.1 mm and ~2.9 mm for the shuttle-lock and magnetic-lock systems respectively. It is interesting to note the very small differences in pistoning between different systems.

2.4.4. Gait deviations associated with pistoning

By convention, the standard gait cycle may be divided into a sequence of phases, as shown in *Figure 2.11* (55).

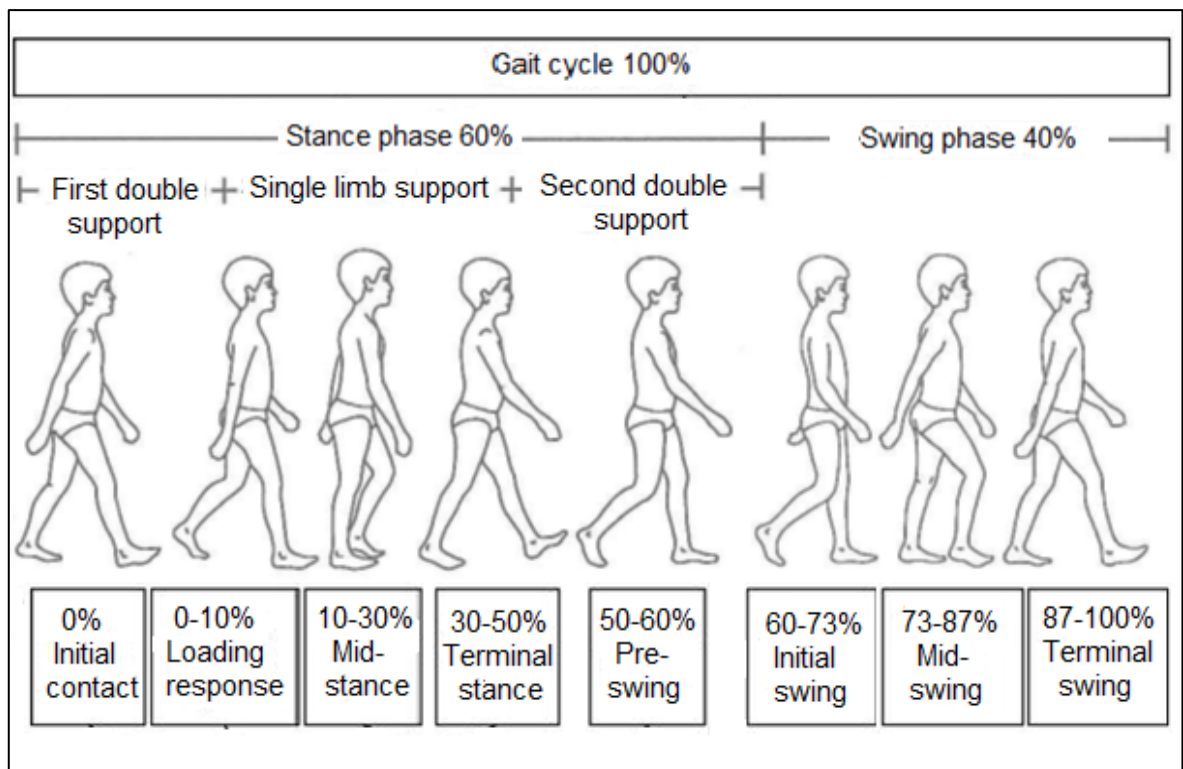


Figure 2.11: Gait cycle (55).

Pistoning during the swing phase will increase the effective length of the prosthetic limb. Amputees may manage this problem through different compensatory strategies, including: a) raising the pelvis on the prosthetic limb side during the swing phase (hip hiking) (56); b) increasing hip and knee joints flexion of the prosthetic limb during the swing phase (57) and/or; c) increasing the plantar-flexion of the sound limb during the stance phase (vaulting gait) (58).

Only one study has explored the relationship between gait deviations and pistoning (21). Eshraghi et al (2014) (21) fitted 13 trans-tibial amputees with SSSS, Shuttle-lock, and Magnetic-lock suspension systems (21). Gait kinematics, GRFs, and pistoning data were obtained using an optical motion capture system and force plates. Each participant was required to complete 5 trials with each suspension system. The main difference across these suspension systems was seen in the prosthetic knee joint kinematics (*Figure 2.12*). The mean (range) of the RoM of the sagittal prosthetic knee joint was $\sim 71^\circ$ (68° to 73°), $\sim 61^\circ$ (59° to 64°), and $\sim 58^\circ$ (57° to 60°) for the SSSS, shuttle-lock, and magnetic-lock suspension systems respectively (*Figure 2.12*). The mean (range) of the peaks of the prosthetic knee joint flexion during the swing phase was $\sim 75^\circ$ (73° to 78°), $\sim 67^\circ$ (65° to 69°), and $\sim 61^\circ$ (59° to 63°) for the SSSS, shuttle-lock, and magnetic-lock suspension systems respectively (*Figure 2.12*). Regarding the GRFs, the main difference between these suspension systems was shown in the vertical component (*Figure 2.13*). The peak load was at its lowest in trials using the magnetic-lock system (*Figure 2.13*). The authors linked these results to the amount of pistoning. However, it is questionable whether the differences in the peaks of the prosthetic knee joint flexion during the swing phase ($\sim 14^\circ$), between the SSSS and magnetic-lock system, could be attributed to quite small differences in pistoning (1.3 mm).

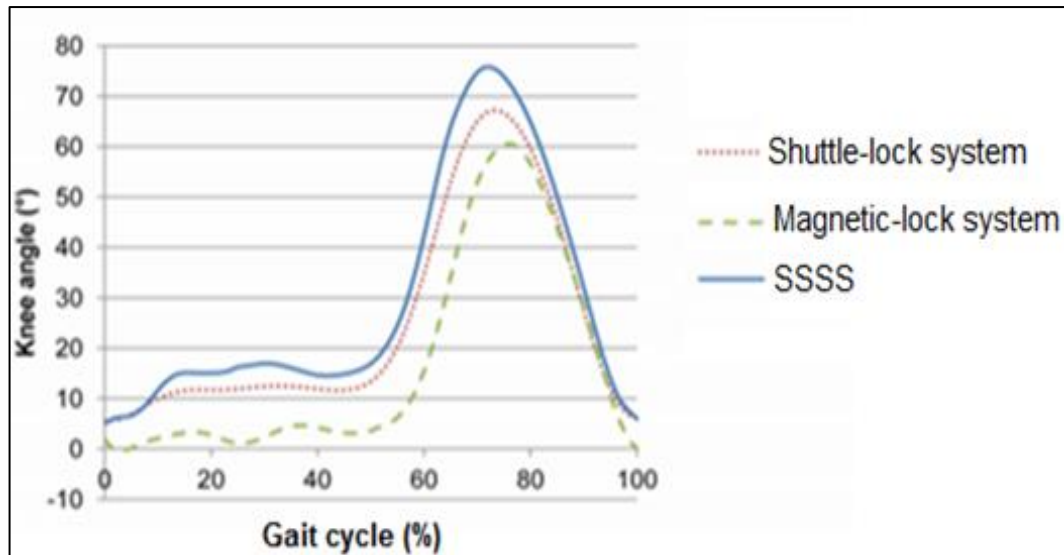


Figure 2.12: Sagittal knee joint angle during gait measured while walking with three different suspension systems (21).

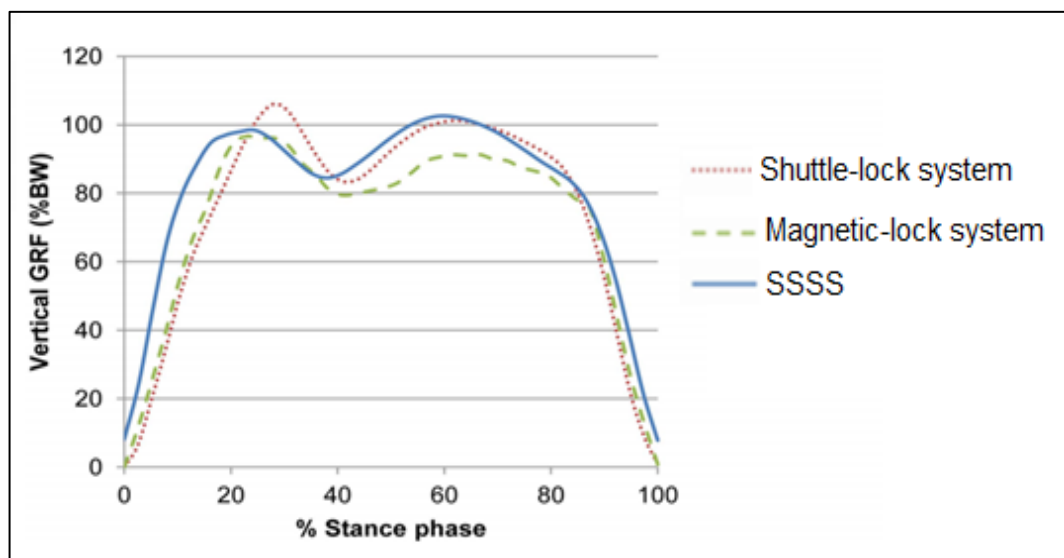


Figure 2.13: Vertical GRFs during stance phase measured while walking with three different suspension systems (21).

In another study, Gholizadeh et al (2014) (59) collected kinematics and GRFs data on 10 unilateral trans-tibial amputees using an optical motion capture system and force plates. Each participant was fitted with the SSSS and Shuttle-lock system. Data were collected for each participant while performing 5 walking trials with each suspension system. Pistoning was assessed by asking participants to self-rate the perceived problems with SSSS and shuttle-lock system using a questionnaire. The

main difference across these suspension systems was seen in the prosthetic knee joint kinematics (*Figure 2.14*). The mean \pm SD of the RoM of the sagittal prosthetic knee joint was $\sim 71^\circ \pm 3.5^\circ$ and $\sim 62^\circ \pm 3.2^\circ$ for the SSSS and shuttle-lock suspension systems respectively (*Figure 2.14*). The mean \pm SD of the peaks of the prosthetic knee joint flexion during the swing phase was $\sim 75^\circ \pm 2.4^\circ$ and $\sim 67^\circ \pm 3.9^\circ$ for the SSSS and shuttle-lock suspension systems respectively (*Figure 2.14*). With respect to the GRFs, the main difference between these suspension systems was shown at the first peak of the vertical component (*Figure 2.15*). The load was lower in trials using the SSSS (*Figure 2.15*). With respect to pistoning, participants reported less pistoning inside the socket while walking with the SSSS compared to the shuttle-lock system. The authors linked the differences in the kinematics to pistoning, suggesting that the differences in the peaks of the prosthetic knee joint flexion during the swing phase ($\sim 15^\circ$), between the SSSS and magnetic-lock system, could be related to quite small amounts of pistoning (1.3 mm), reported in Eshraghi et al (2014) (21). However, pistoning was not objectively measured, raising questions about the validity of their conclusions (21).

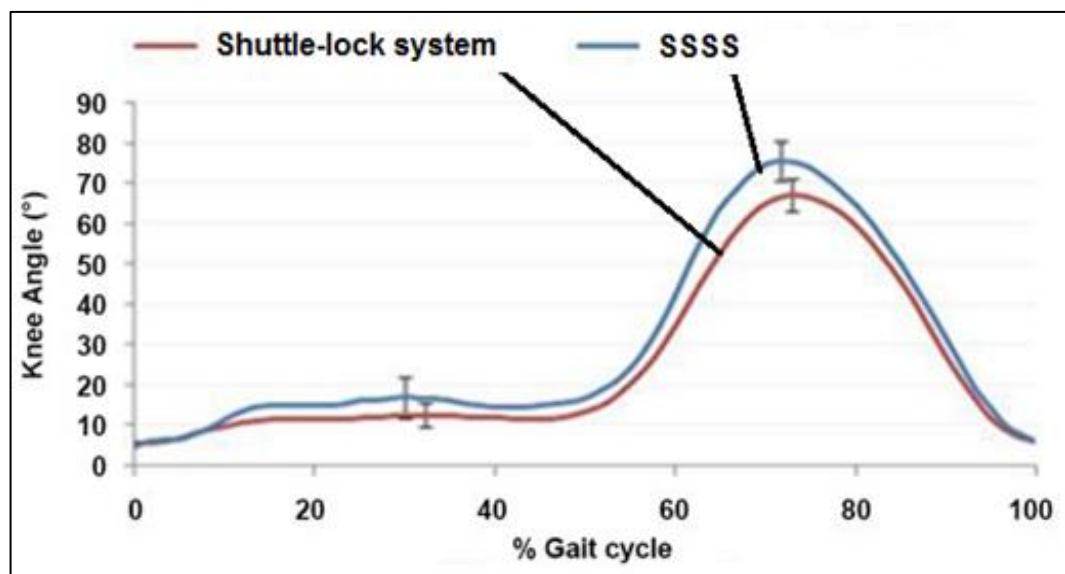


Figure 2.14: Sagittal knee joint angle during gait measured while walking with two different suspension systems (Mean \pm SD) (59).

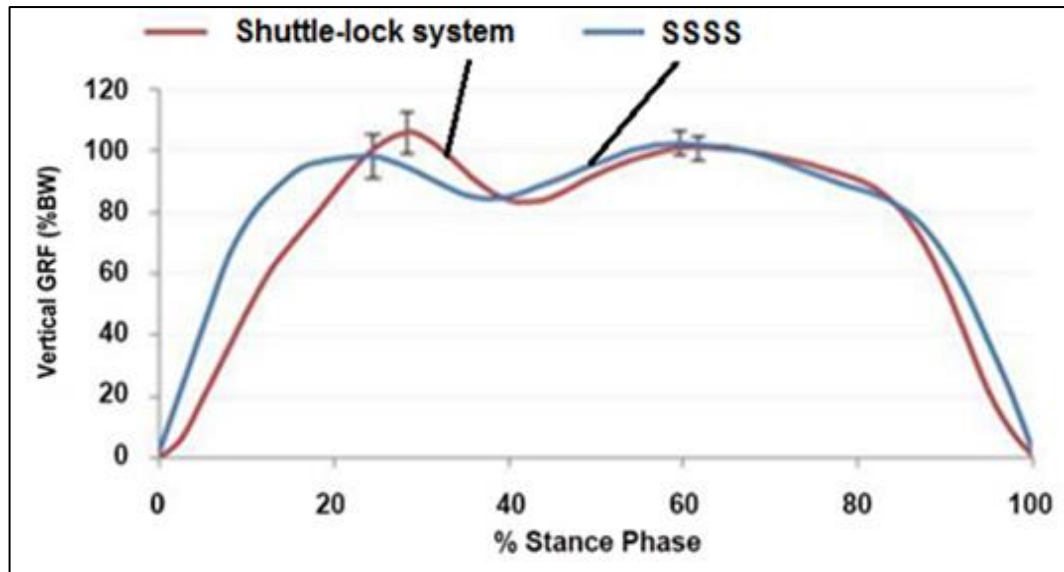


Figure 2.15: Vertical GRFs during stance phase measured while walking with two different suspension systems (Mean \pm SD) (59).

In conclusion, pistoning is the vertical displacement of the residuum relative to the socket (34). It results from forces acting on a compliant residuum-socket interface during walking (37). Pistoning may be the cause of injury (51) and pain (46), and reduced function (46, 52). The magnitude of pistoning has been assessed in both static (*Figure 2.4*) (34, 53) and walking (26) conditions. Different methods have been used to assess pistoning under static loading conditions, including radiological systems (X-ray and CT system) (22, 53), photographic methods (34, 38), a measuring tape (43), and an optical motion capture system (30, 31). Other methods include use of a noncontact photoelectric sensor (26), video-fluoroscopy (32), and a linear potentiometer (28). The magnitude of pistoning, in trans-tibial prosthetic sockets appears to be affected by the suspension system type, but the quality of the studies in this area is generally low (*Figure 2.10*).

Pistoning may increase the effective length of the prosthetic limb, leading to compensatory movements (56-58). Only two studies have linked the amount of pistoning to these compensatory mechanism (21, 59), but their results are open to question.

2.5. Residuum volume fluctuations

2.5.1. Introduction

Homeostasis is the process by which the body maintains a constant internal environment, including the maintenance of fluid volume (60). The major body fluid compartments are intracellular and extracellular. Extracellular fluid, can be divided into plasma, in which blood cells are suspended and interstitial fluid, the fluid surrounding cells (60, 61). Different homeostatic mechanisms regulate the balance of these fluids (60, 61). Other higher level systems, such as the lymphatic system and skin also help to maintain the body's fluid balance (60).

During gait, muscle contractions act to balance the effects of external forces on the distribution of fluid in the body (62). For example, gravitational and inertial forces will tend to pull internal fluids distally towards the calf area. Calf muscle contractions then help to pump this fluid back to the heart by: 1) changing the limb orientation through movement and 2) increasing the pressure in vessels carrying returning fluid during muscle contraction (62, 63). As will be explained below, following an amputation, the body's homeostatic function is disrupted.

One of the most important implications for post-amputation of lower limbs is Residuum Volume Fluctuations (RVFs) (64). RVFs are an increase or decrease in the volume of the body fluid inside the residuum (64). The causes of excessive RVFs are complex, but believed to include both intrinsic and extrinsic factors. In the case of trans-tibial limb loss, the focus for this thesis, the intrinsic factors include: a) inadequate pumping of the fluid due to partial absence of the calf muscles and post-amputation muscle atrophy (63); b) absence of parts of the vascular and lymphatic systems; and c) medication, which can affect vasodilation and vasoconstriction. Extrinsic factors include the forces acting on the residuum and other environmental factors, such as air pressure inside the socket (2).

It is believed that changes to extracellular fluid is the primary cause of short-term RVFs (within a test session (<1 day)), while the changes in intracellular fluid lead to longer term fluctuations in residuum volume (between sessions (>1 day)) (3). As

explained later in this thesis, the short-term changes of RVFs are the main focus for the proposed study.

The following section discusses the impact of in-socket air pressure on short-term RVFs.

Board et al (2001) (2) studied amputee gait comparing two suspension systems (SSSS and VASS - activating the vacuum pump) (34). They found residuum volume was better maintained when walking with the VASS suspension system than with the SSSS and suggested that the in-socket vacuum pressure may draw more fluid into the residuum and decrease the fluid driven out of the residuum. Beil et al (2002) (65) proposed that below-atmosphere in-socket air pressure may reduce the reduction in residuum volume while walking with a prosthesis (65). However, residuum volume changes were not measured in this study. Sanders et al (50) used a bio-impedance-based system to assess the fluid volume changes inside the residuum while using different suspension systems (SSSS and VASS). The system which created the lowest air pressure was shown to be the most effective in reducing the reduction in fluid volume in the residuum seen during periods of upright mobility. Although the mechanisms of fluid circulation in the residuum are still unclear, there is some suggestion from the literature that maintaining a low in-socket air pressure may help to reduce residuum volume reduction.

2.5.2. Residuum volume measurement techniques

Residuum volume is traditionally estimated based on the circumferences and/or the distances between the anatomical landmarks of the residuum (66). Residuum volume can be directly measured using the water displacement method, in which the volume of water displaced by immersing the residuum to a defined level in water is calculated (67). A similar approach, using a cast of the residuum combined with the water displacement technique has also been reported (68).

Ultrasound imaging has also been used to evaluate residuum volume. The technique employed a water tank and a noncontact ultrasound sensor (69). The ultrasound sensor was moved around the residuum and software used to reconstruct a 3-Dimensional (3D) image of the residuum (69) (see *Figure 2.16*).

Radiological systems (CT and Magnetic Resonance Imaging (MRI)) have also been used to calculate the residuum volume (70, 71). However, CT scanning involves exposure to ionising radiation and MRI is limited due to the cost of accessing MRI facilities.

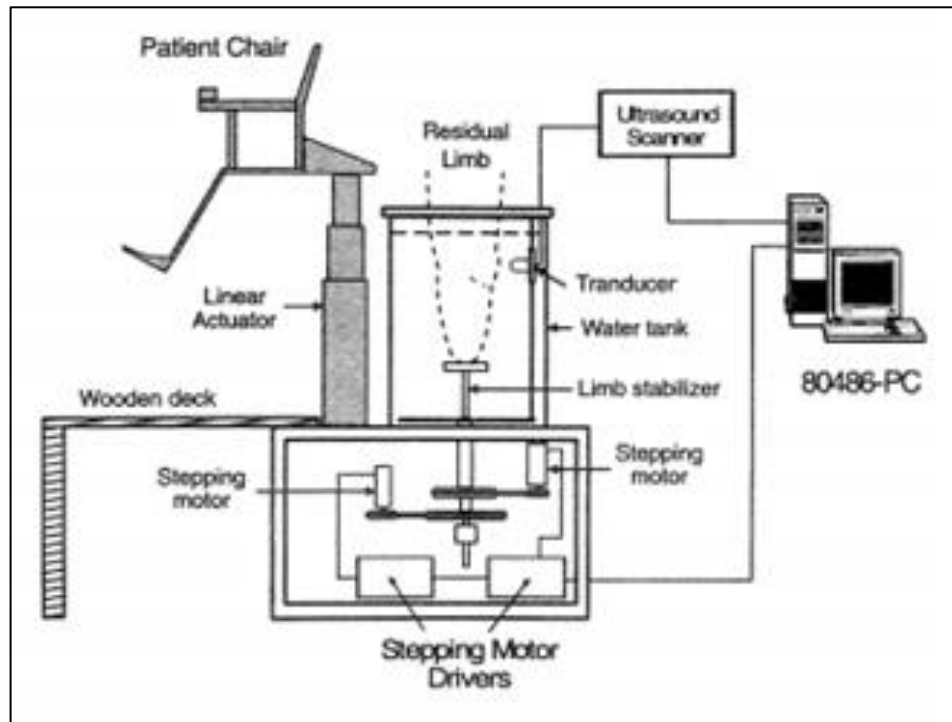


Figure 2.16: The main components of the ultrasonic scanning system for measuring the residuum volume (69).

Sanders et al (2007) (72) introduced a bio-impedance-based system as a way of estimating the fluid volume changes inside the residuum. This system can be applied during the amputee's activity, while wearing their prosthesis. The bio-impedance system contains four strip electrodes, attached as shown in *Figure 2.17*. One pair is used to apply a current at a range of different frequencies, and the other to measure the resultant voltage (72). A computer model is used to estimate fluid volume changes from the voltages measured at different frequencies (72) (*Figure 2.17*).

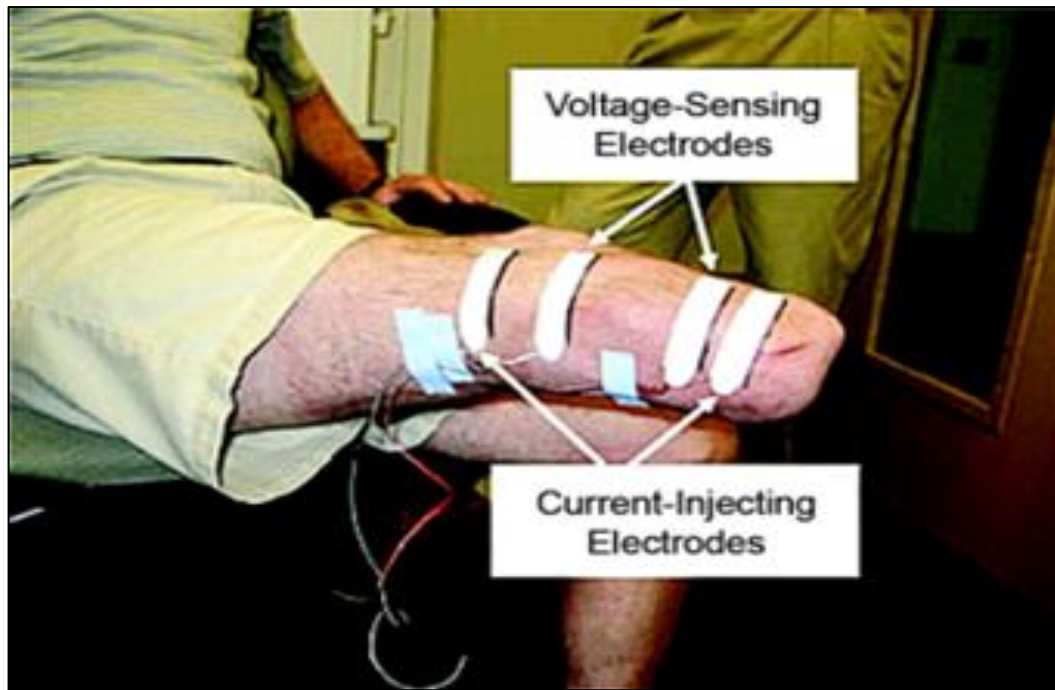


Figure 2.17: The bio-impedance-based system for measuring the fluid volume changes inside the residuum (72).

3D optical surface scanner systems have also been used to capture the residuum shape (73). In the earliest reported study, the amputee was seated in a large purpose-built measurement system (73), as shown in *Figure 2.18*. However, more recent studies have reported the use of much more compact systems.

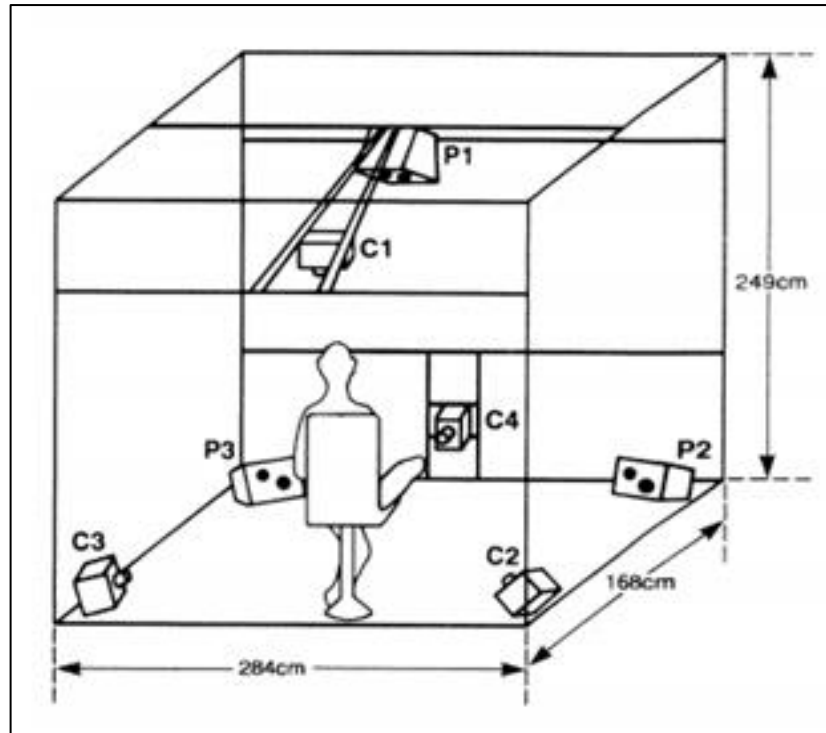


Figure 2.18: 3D optical surface scanner system to measure the residuum volume of an amputee. The system comprises five cameras(C1-5) and projectors (P1-3) (73).

Building on this approach, laser-based scanner systems are now commonly used to capture the residuum geometry (*Figure 2.19*) (1). The residuum is scanned using a hand scanner which projects laser light onto the residuum. The reflected light is used by the system to build a 3D model, based on the geometry of the scanned object (residuum). Once the scanning is finished, the residuum volume can be calculated from a 3D model derived from the scan data (1).



Figure 2.19: Scanning an amputee's residuum using a laser-based scanner system (74).

A repeatability study (54) comparing the repeatability of four different techniques (water displacement, optical scanning, anthropometric measurement and laser-based scanner system), showed that volume measurement using a laser-based scanner system was associated with the highest repeatability. Also, use of the laser-based scanner system is not associated with any side effects on the amputees, is both easily portable and fast to use.

2.5.3. Underlying causes of short-term RVFs

Studies have shown that both activity and residuum orientation during periods of inactivity impact on residuum volume over short time periods (up to 1 day). The extent and time course of these changes remains a matter of research, summarised here.

In most of these studies (50, 64, 75, 76), amputee subjects have been invited to visit the laboratory and, following a short period of rest, the initial volume of the residuum

($V_{baseline}$) was measured², using one of the techniques mentioned above. Subjects were then typically invited to spend a period of time (ranging from 90 seconds to 5 minutes) walking, standing and/or sitting while wearing their prosthesis. Following this, subjects were asked to remove their prosthesis and the volume of their residuum was re-measured immediately (V_{doff})³. The percentage change of the residuum volume was calculated as below.

$$\text{Change in residuum volume} = \frac{V_{doff} - V_{baseline}}{V_{baseline}} * 100\% \quad (1)$$

In studies focused on the time course of changes in volume following socket doffing, volume is measured at a series of time points following doffing ($V_{doff + t}$, where t is the time in minutes post doffing).

Figure 2.20 shows how different activities influence the fluid volume inside the residuum.

² For the purpose of this thesis, the initial volume was defined as ($V_{baseline}$).

³ Doffing the prosthesis was not required to assess the RVFs while using the bio-impedance technique.

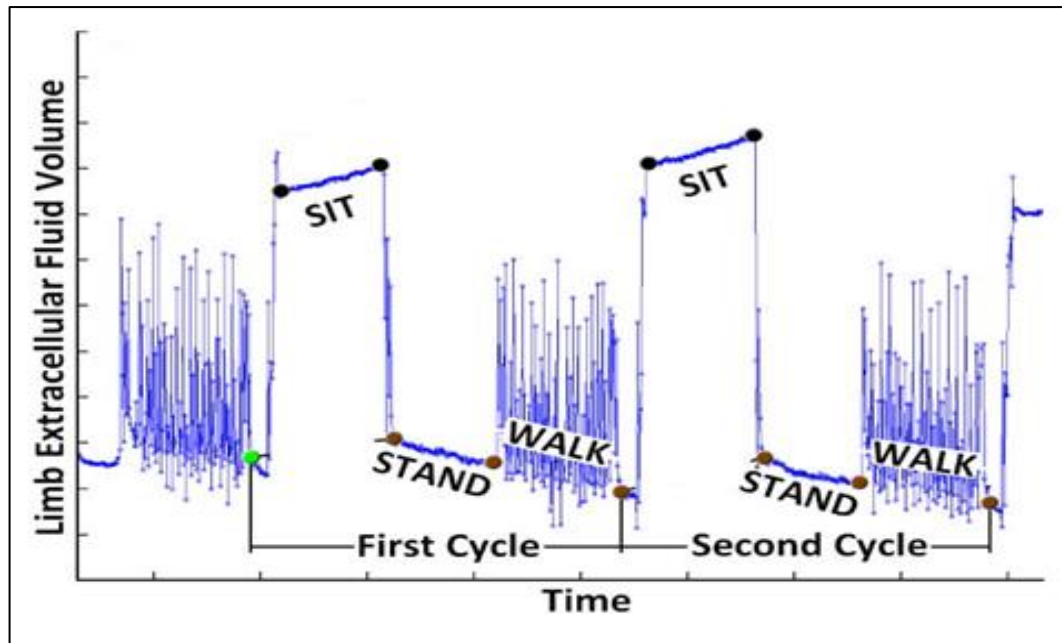


Figure 2.20: The effects of walking, standing, and resting on the fluid volume changes inside the residuum. A cycle of sitting (90 Sec), standing (90 Sec), walking (90 Sec), and standing (10 sec) was applied five times during this study. Residuum volume changes was assessed using the bio-impedance technique (50).

Zachariah et al (2004) (64) studied the short-term recovery of volume in the trans-tibial residuum of six participants. A 3D optical scanner was used to assess residuum volume. The participant attended for set-up and training sessions prior to the data collection day. Data was collected on two sessions, 14 days apart. On the data collection day, the participant was seated for 10 min while wearing his prosthesis, to allow the residuum volume to reach its steady state. Then, the participant doffed his prosthesis and liner and 3 residuum scans were taken immediately (V_{baseline}), spaced 1 minute apart. The prosthesis was then re-donned and the participant walked at comfortable walking speed (CWS) for 200 m (4-5 minutes approximately). The participant then doffed his prosthesis and liner and 3 scans of the residuum were taken, as before (V_{doff}). The participant remained seated and scans of his residuum were taken after 5, 10, 15, 20, 25, 30, and 35 minutes⁴.

⁴ In order to estimate the time taken for the residuum volume to return to its steady state volume following a period of upright mobility

Finally, after the 35 minutes scan, 4 scans were taken (1 min apart)⁵. The results showed that the residuum volume of all six participants increased after doffing the prosthesis by between 2.4% and 10.9% (mean = 6%). For five of the six participants, the maximum rate of residuum volume increase occurred within the first 8 minutes following doffing the prosthesis. In four of the six participants, 95% of the V_{baseline} was reached within the first 8 minutes following doffing the prosthesis.

Figure 2.21 shows the time course of volume change post doffing the prosthesis (socket and liner), for one participant, over 35 minutes of resting.

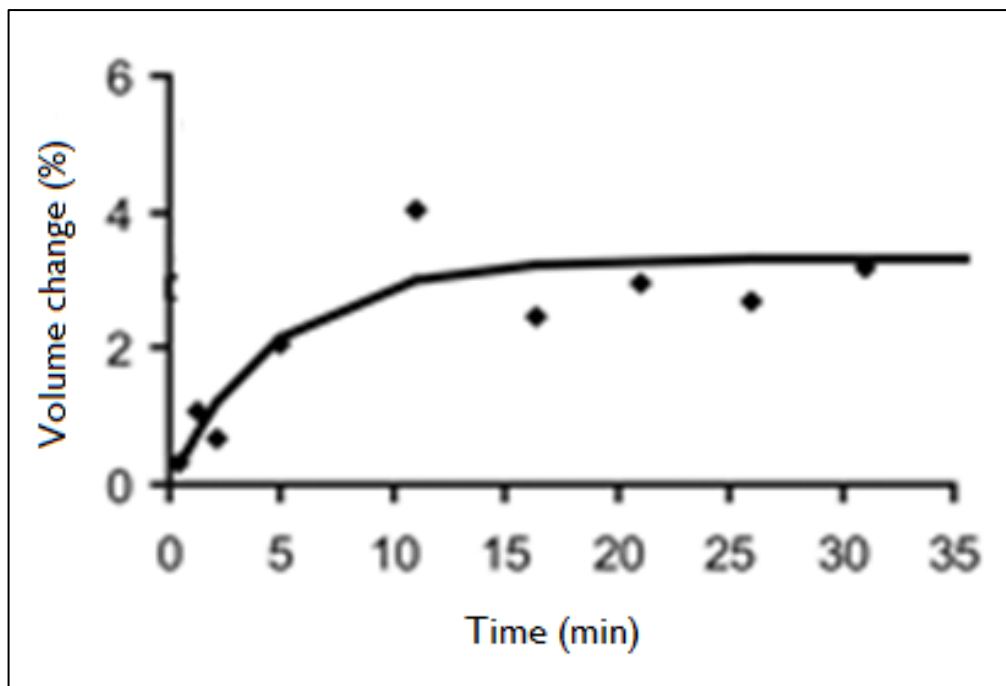


Figure 2.21: Residuum volume change (positive means increase relative to baseline) over a 35 minute period following doffing the prosthesis (64). (An example result for one participant).

⁵ The purpose of these last 4 scans was to assess the accuracy of the 3D optical scanner

2.5.4. Passive methods for managing the short-term reduction in residuum volume

Different methods are used to manage the short-term reduction in residuum volume during walking, with extra socks or the addition of an extra liner being commonly used (76). However, adding socks may increase the pressure onto the residuum and hence lead to a worsening of the problem (76). Doffing the prosthesis to recover the residuum volume is also used, but clearly is far from ideal (77).

As the design of the suspension system impacts on the loads acting on the residuum, a number of studies have compared the effects of different suspension systems on maintaining residuum volume over short-term. In particular, a number of studies have investigated the vacuum-based suspension systems, which have been developed with the aim of maintaining a low in-socket air pressure. These can be categorised as 1) Passive controlled (Suction Socket Suspension System (SSSS)) with expulsion valve (2, 25, 30); and 2) Active controlled (Vacuum-Assisted Suspension System (VASS)) which use an electrical pump to maintain a set in-socket air pressure, such as Limb-Logic Communicator (2, 29)⁶. The former is easy to use, cosmetic, and light weight; the latter is higher cost and special training may be required to fit the system.

2.5.5. The impacts of vacuum-assisted suspension systems on maintaining residuum volume and amputees' comfort

The use of VASS appears to have a direct impact on preserving the residuum volume, as described below.

Board et al (2001) took a cast of the residuum to find V_{baseline} , prior to walking. The participant was then asked to walk for 30 min on a treadmill. Another cast was taken immediately after walking to measure V_{doff} . Each participant repeated this protocol twice, once with VASS and once with SSSS. The result showed that residuum

⁶ Already discussed under the sub-heading (Lower limb prostheses/ Suspension systems)

volume increased by an average (range) of 3.7% (-1.6% to 8.5%) and decreased by 6.5% (-11.3% to -1.7%), compared to V_{baseline} , after 30 minutes of walking, with VASS and SSSS respectively (*Figure 2.22*) (2).

In another study, Gerschutz et al (2010) (1) compared short-term changes in residuum volume while wearing SSSS and VASS and long term changes while wearing the VASS. The study involved a single male participant (K-2 mobility grade, 9 years post amputation due to diabetes) visiting the lab 6 times over the course of approximately 4 months. On the first 3 visits and on the 5th visit the subject was tested while wearing the SSSS, and the other 2 visits, the subject wore the VASS. In-between visits the subject wore the VASS. The paper fails to clearly report the methods, but as far as the author can tell on each occasion the residuum volume was measured twice (10 minutes apart) following socket doffing when the participant arrived (V_{baseline}), and twice (10 minutes apart) immediately following a 2 hour period during which the subject walked at least 250 steps (1). They reported that residuum volume decreased by an average (range) of 0.4% (-0.3% to -0.5%) and 2.4% (-1.6% to -2.9%), compared to V_{baseline} , for VASS and SSSS respectively, when the residuum volume was measured immediately after doffing the prosthesis (*Figure 2.22*). Also, they found an improvement in residuum volume retention and wound healing with long-term VASS usage (1).

Sanders et al. (2011) (3) studied the effects of two different socket suspension systems on residuum volume as follows. Three male participants with trans-tibial amputation were recruited, one with vascular problems (K-3), the others were healthy (K-4). Participants were fitted with the VASS 3 to 4 weeks before the testing day. The testing protocol was as follows: Vacuum Switched-Off (SSSS), sit 2 min, stand 3 min, walk 3 min, Vacuum Switched-On (VASS), walk 3 min, sit 2 min, stand 3 min, and walk 3 min (3). Changing in residuum volume was obtained using a bio-impedance technique. They found that the residuum volume increased by an average (range) of 0.3% (-0.6% to 1.2%) and decreased by 0.1% (-0.5% to 0.3%) while using VASS and SSSS respectively (3).

Figure 2.22 shows the results from literature of the RVFs while using vacuum-based suspension systems.

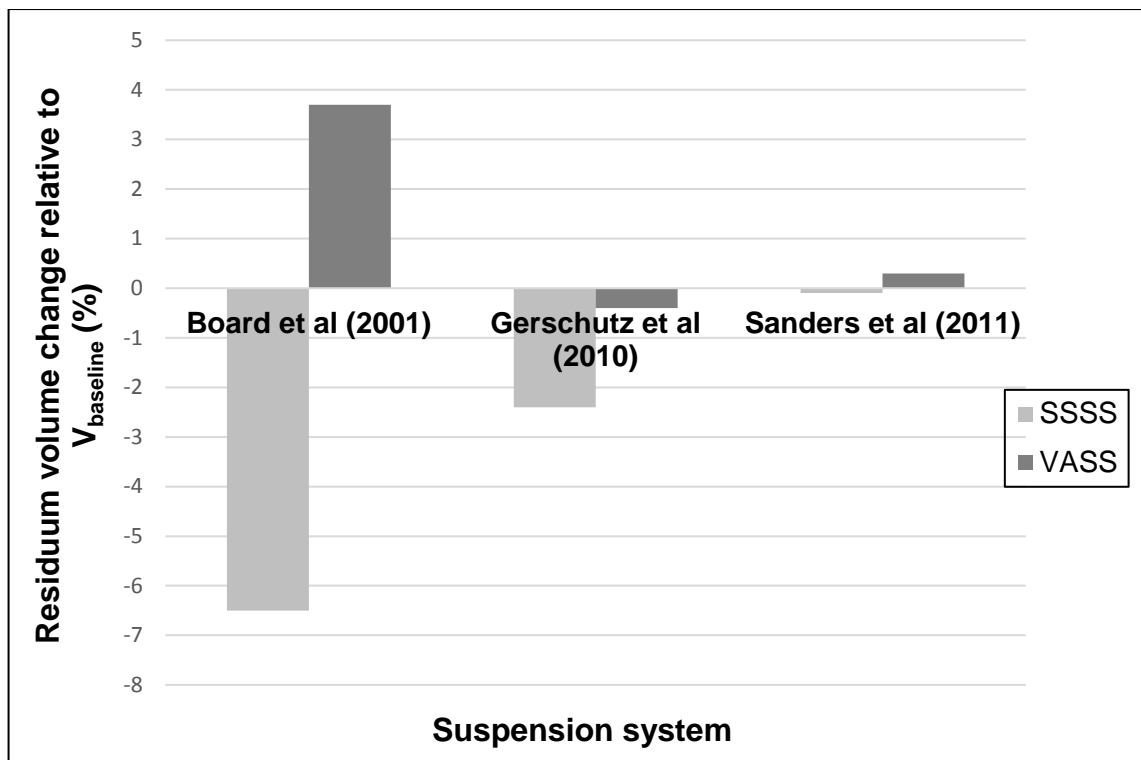


Figure 2.22: Results from literature of the residuum volume change relative to $V_{baseline}$ (%), calculated using formula (1). Positive and negative signs indicate increase and decrease in residuum volume respectively (1-3). Note – different protocols were used in each study.

A few papers have highlighted the long-term consequences of using a VASS. Wearing a VASS was shown to improve gait parameters (46, 78) and self-reported prosthesis control (47) compared to a shuttle-lock system (78). More importantly, the VASS may help with residuum wound healing, particularly at the distal end (1, 47, 79). The proposed mechanism by which this occurs is believed to be an increase in the blood supply in the residuum due to the reduced in-socket air pressure.

In conclusion, RVFs are a common occurrence for amputees (64) and are due increase/decrease in the fluid volume inside the residuum (64). In general, the causes of RVFs can be classified to: 1) intrinsic factors, such as muscle atrophy (63) and; 2) extrinsic factors, such as air pressure inside the socket (2). Changes in extracellular fluid lead to short-term RVFs (<1 day), while the changes in intracellular fluid lead to longer term RVFs (>1 day) (3). The former is the focus for this thesis.

Different techniques have been used to estimate the residuum volume. These methods include ultrasound imaging (69), radiological systems (CT and MRI) (70, 71), a bio-impedance-based system (72), and 3D optical surface scanner systems (73). The laser-based scanner systems now commonly used to assess the residuum volume (1) appear to have the highest reliability (54), are easily portable and fast to use, and have no side effects on the amputees.

Studies have shown the impact of both activity and residuum orientation during periods of inactivity on the residuum volume over short time periods (>1 day). The extent and time course of these changes remains a matter of research. Zachariah et al (2004) (64) concluded that 8 minutes of resting whilst the prosthesis doffed (and the liner) is recommended to achieve a relatively homeostatic condition of residuum volume (64). In another study, Sanders et al (2012) (77) founded that resting while doffing the prosthesis, but not the liner, for 4.3 minutes can achieve a reasonably stable residuum volume (77). Very little research has been done on the amount of upright time needed to cause RVFs to occur, but one study showed that walking a distance of 200 meters (~ 4 to 5 minutes) was sufficient to show a measurable effect (64).

Common methods are used to manage the short-term reduction in residuum volume, such as adding extra socks/liner or doffing the prosthesis (76). However, the former method may increase the pressure onto the residuum and hence lead to a worsening of the problem (76). The latter is a way from ideal (77). A few papers have suggested that a low in-socket air pressure may be beneficial in maintaining residuum volume over short-term. Board et al (2001) (2) and Beil et al (2002) (65) both proposed that low in-socket air pressure may reduce the short-term loss in residuum volume experienced by amputees. Results from Board et al (2001) (2), Gerschutz et al (2010) (1), and Sanders et al (50) seemed to support this. This led to the design of active and passive vacuum-based suspension systems (2). The passive system is easy to use, cosmetically appealing, and light weight. Whereas the active system is higher cost and special training may be required to fit the system.

Studies compared between the VASS and SSSS in terms of maintaining residuum volume (i.e., residuum volume change relative to V_{baseline}) (*Figure 2.22*) (1-3). The differences between these papers could be due to the accuracy of used techniques to assess the RVFs and the small heterogeneous samples. Board et al (2001) (2) used a casting method with the water displacement technique, while Gerschütz et al (2010) (25) and Sanders et al (2011) (3) used laser-based scanner system and bio-impedance techniques respectively. Regarding the long-term consequences of using a VASS. VASS can improve gait (46, 78), comfort and self-reported prosthesis control (47) compared to the shuttle-lock system (78). VASS can also enhance the residuum wound healing; possibly by increasing the blood supply in the residuum due to vacuum pressure (1, 47, 79). Therefore, there is some evidence that the VASS can reduce the reduction in residuum volume during upright mobility, maintain residuum-socket fit and hence, decrease the amount of pistoning, subsequently, reducing pain and injuries.

2.6. Aims and objectives

As highlighted in the previous section, a small number of studies have shown that reducing the in-socket air pressure may help to reduce the short-term reduction in residuum volume. However, our understanding of the factors which influence changes in residuum volume remains very limited. For example, it is not known whether peak pressure in a gait cycle, or average pressure is the most important factor in determining residuum volume changes. Further, although a below atmospheric in-socket air pressure has been shown to be effective, there is anecdotal evidence to suggest that amputees may find a very low in-socket air pressure to be uncomfortable or even risk tissue damage.

As explained in the following chapter (Chapter 3), there is the possibility of reducing the in-socket air pressure changes during gait in a passive system (SSSS) by designing in a void into the socket. In brief, based on Boyle's law, by introducing a void into the socket the total air volume is increased and hence relative change in air volume and hence pressure resulting from movement of the residuum in the socket, may be reduced. However, how the pressure profile might compare to an

active system is not known, nor are the effects on RVFs, patient comfort, and gait parameters.

Based on the previous discussion, passive systems (SSSS) offer the potential to reduce the short-term residuum volume reductions and consequent increase in pistoning experienced by amputees. Active systems (VASS) offer a good alternative, but are expensive and in some cases, may not be necessary.

Therefore, the aims of the main study were to:

1. Design and build a test prosthesis that allow participants to be tested while walking with a SSSS, a modified SSSS, and a VASS.
2. Use the new prosthesis to compare the performance of the SSSS, modified SSSS, and VASS in terms of:
 - Maintenance of residuum volume;
 - Comfort and;
 - Gait kinematics and GRFs.

Chapter three introduces the Instrumented Trans-tibial Prosthesis (ITTP).

Chapter 3: Instrumented Trans-tibial Prosthesis (ITTP)

3.1. Introduction

In order for the experimental analysis to take place, a bespoke 'test prosthesis' was required. This chapter outlines the development of an Instrumented Trans-tibial Prosthesis (ITTP).

The ITTP was designed to allow participants to be tested while walking with a Suction Socket Suspension System (SSSS), a modified SSSS, and a Vacuum-Assisted Suspension System (VASS). In the first part of this chapter, a very simple model will be developed. This model is a useful starting point with which to estimate the effects of distal void volume on the in-socket air pressure during gait and allowed suitable distal void volumes to be selected.

In the second part of this chapter, the geometry of the required distal 'plugs' for the socket will be calculated, based on the chosen initial distal void volume. Subsequently, the new test-socket design and the components of the ITTP will then be presented. Finally, the minimum residuum-ground clearance to be considered in the recruitment criteria for the final study was calculated.

The aims of this chapter were to:

- 1) Estimate the distal void volume that, when introduced would significantly reduce the in-socket air pressure fluctuations while walking;
- 2) Design a test-socket based on the finding in 1;
- 3) Define the components of the ITTP and;
- 4) Estimate the minimum residuum-ground clearance to allow for full assembly of the ITTP.

3.2. Specification of maximum and minimum distal void volumes

In order to investigate the hypothesis outlined in Chapter 2, the first step was to decide on a suitable distal void volume. The volume should be of a sufficient size, such that when added to a standard socket, there would be significantly reduced within-gait-cycle fluctuations in in-socket air pressure, compared to the standard socket configuration.

In order to define the distal void volume, a number of assumptions were made. Firstly, it was assumed that the residuum 'pistons', i.e. moves up and down within the socket as a result of loading and unloading during gait. As the residuum moves up the empty volume at the distal end of the socket is assumed to increase; conversely, as the residuum moves down, the empty volume at the distal end of the socket should decrease accordingly. A simple model was developed to guide the selection of the volume, as shown in *Figure 3.1*.

Standard protocol tends to define the relative residuum/socket displacement, under five different loading conditions; correspondingly, we therefore define the relevant variables associated with each condition below:

Table 3.1: Definitions of variables.

Loading condition	Distance from distal end of residuum to distal end of socket	Distal void volume	In-socket air pressure
Single Limb Support (SLS) F_0	d_0	V_0	P_0
Double Limb Support (DLS) F_1	d_1	V_1	P_1
Un-Loaded (UL) F_2	d_2	V_2	P_2
30N tensile force F_3	d_3	V_3	P_3
90N tensile force F_4	d_4	V_4	P_4

Figure 3.1 shows a schematic of a socket and residuum. It was assumed that, at a defined maximum load (SLS, F_0) there remains a non-zero distance between the distal end of the residuum and the interior socket wall and hence a non-zero distal volume.

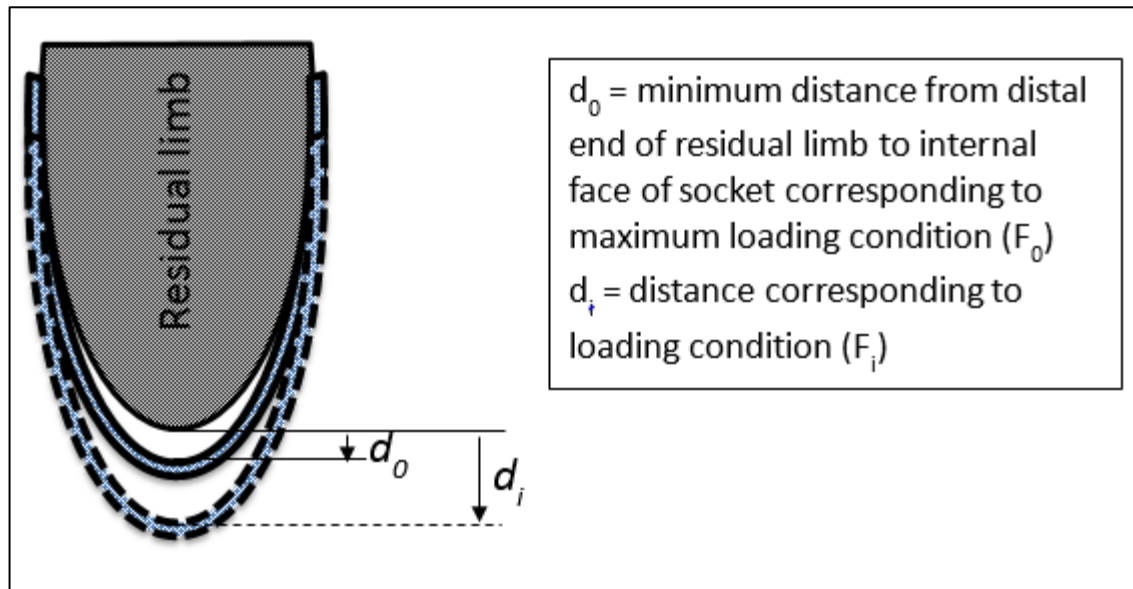


Figure 3.1: Schematic of residuum displacements relative to socket.

Relevant data relating to the displacement of the residuum within the socket during prosthesis usage was limited although Brunelli et al (2013) (35) presented usable data⁷ on pistoning under relative loads observed in a trans-tibial amputee with a SSSS (Figure 3.2 and Figure 3.3). The displacement of the socket relative to the residuum was defined as zero under the SLS condition (see Table 3.1). Relevant data points for displacement at -405 N (DLS) and 90N (F_4) were estimated based on linear fits to the experimental data (Figure 3.2). However, DLS (F_1) was calculated from SLS (F_0) and UL (F_2). Also, 90N tensile load (F_4) was extrapolated from UL (F_2) and 30N tensile load (F_3).

Figure 3.2 shows the amount of residuum displacements while applying different loads and using SSSS in trans-tibial sockets.

⁷ Usable data means loading conditions and displacements were clearly defined.

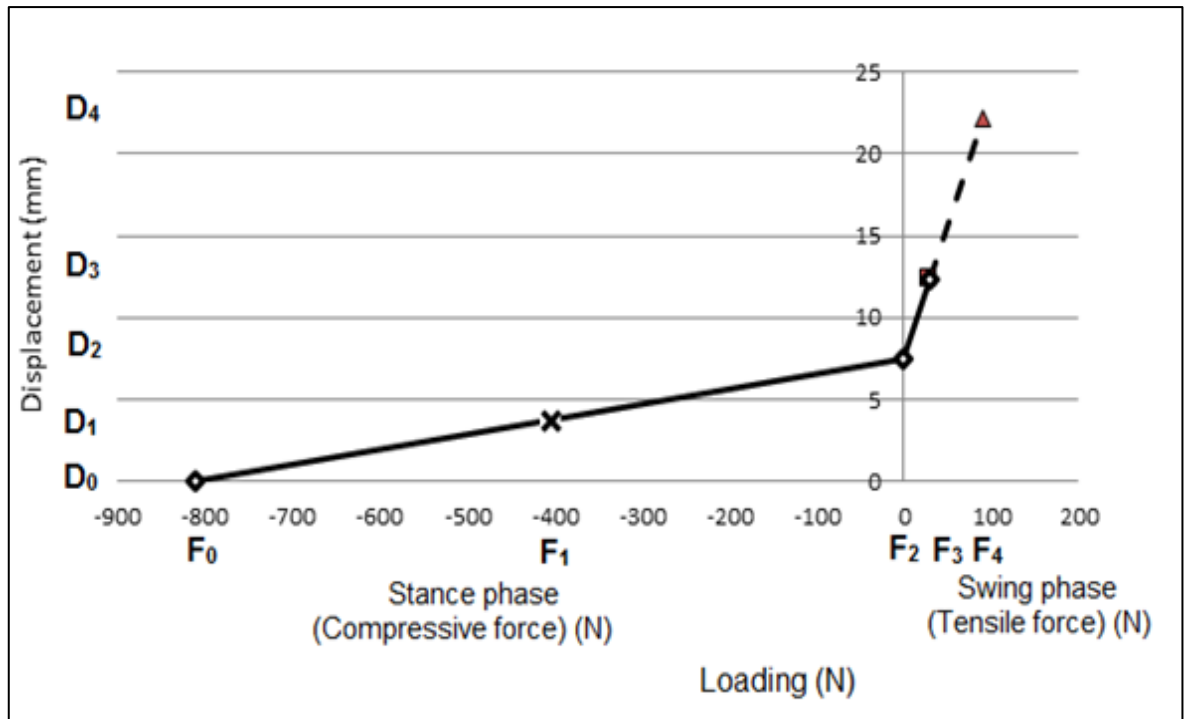


Figure 3.2: Load-displacement data from Brunelli et al 2013 (35)⁸.

Figure 3.3 shows an example of loading conditions during experiment.



Figure 3.3: Loading cases from Brunelli et al 2013 (35). Left – SLS; middle - UL; and right – 30N tensile load.

⁸ In this study, the results of SSSS with sleeve suspension was considered. The reason was using the Limb-Logic Communicator will require a sleeve suspension to seal the system, in the following main study.

Having identified the displacement of the residuum relative to the socket during key points of the gait cycle, the next stage of the specification process was to develop a displacement-distal void volume relationship.

To begin with, we made a basic assumption that the residuum could be considered as approximately circular in cross section in the distal section of the socket. Therefore, changes in distal void volume during pistoning would be approximately equal to the cross-sectional area of the residuum multiplied by its displacement relative to the socket, outlined in the section above.

As described in Appendix A, models from a laser-based scanner system of 7 previously captured trans-tibial residuums, as well as information on usual prosthetic practice were used to estimate:

- a) The average cross sectional area and;
- b) The range of initial (unloaded) distal air gaps (V_2) built into typical trans-tibial amputee sockets.

The mean cross-sectional area was 0.006 m^2 and hence we could assume that the change in volume with pistoning could be described as:

$$\Delta V = 0.006 * d \quad (2)$$

This relationship allowed for an estimation of distal void volume, as a function of initial distal void volume (V_2) and displacement of the residuum within the socket.

The findings described in Appendix A suggest a typical initial (unloaded) air gap volume, V_2 is around 0 - 60 ml.

Table 3.2 showing $V_{0,1,3,4}$ as a function of different V_2 .

Table 3.2: Effects of the initial distal void volume (V_2) on the distal void volume $V_{0,1,3,4}$ over gait.

V_2 (mL)	V_0 (mL)	V_1 (mL)	V_3 (mL)	V_4 (mL)
50	5	27	79	138
60	15	37	89	148
100	55	77	129	188
150	105	127	179	238
200	155	177	229	288

Finally, a known in-socket air pressure value at a specified volume was required. It was assumed that P_1 was equal to atmospheric pressure (101 KPa). This assumption was based on the clinical practice of amputees pressing the manual expulsion valve to equalise in-socket pressure with atmospheric pressure while standing on both lower limbs⁹ (DLS).

Assuming adiabatic conditions apply and no air leakage from the system, we can assume that Boyle's law applies:

$$P_1 V_1 = P_0 V_0 = P_4 V_4 \quad (3)$$

We can therefore use the known pressure P_1 and volumes, $V_{1,0,4}$ (as a function of V_2 and d) to calculate the maximum pressure change ($P_4 - P_0$) over gait for a range of values of V_2 , as shown in *Figure 3.4*.

Figure 3.4 shows the effects of the initial distal void volume (V_2) on the in-socket air pressure change (ΔP) over gait. ΔP is calculated as the difference between P_4 and P_0 .

⁹ Prosthetic and sound limbs

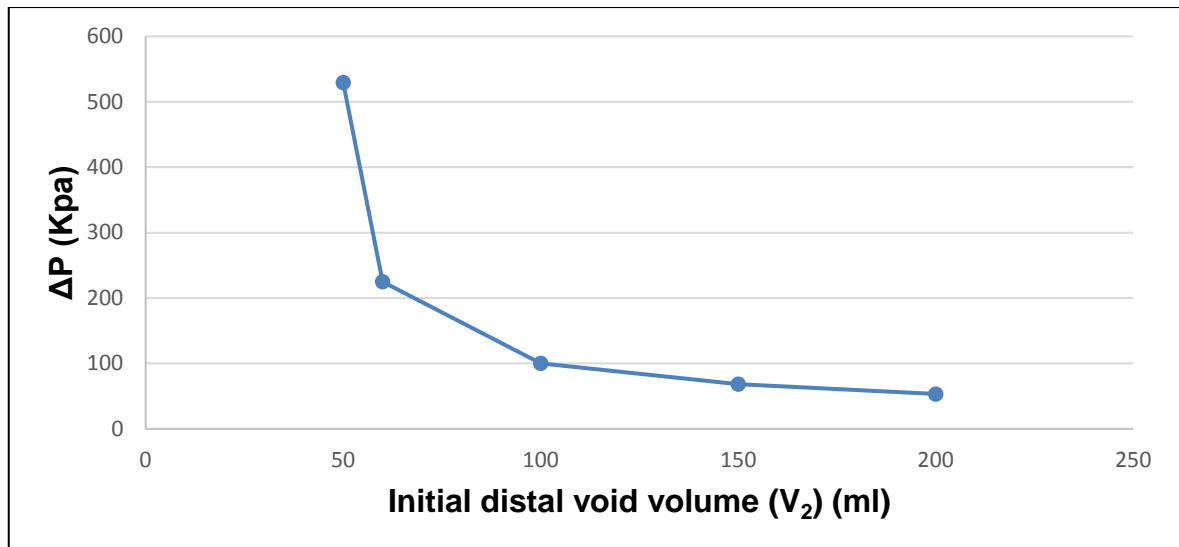


Figure 3.4: Effects of the initial distal void volume (V_2) on the in-socket air pressure change (ΔP) over gait.

Based on the above, assuming an original $V_{2 \text{ (small)}}$ of around 0 - 60 ml¹⁰, then an additional 100 ml (to make $V_{2 \text{ (large)}}$ = ~100 - 160 ml) was selected to give a reasonable likelihood of a significantly reduced in-socket air pressure change over gait.

3.3. Distal void geometry

In order to compare the performance of the SSSS, modified SSSS, and VASS in the main study, described in (Chapter 6: Investigation of the effects of a novel passive socket system on short-term changes in residuum volume, comfort, and gait kinematics and ground reaction forces: A preliminary study in trans-tibial amputees); a new test-socket design was required.

The experimental socket was to accommodate the additional large volume, whose value was calculated above, in a cylindrical extension on the distal end of the socket. A suitably sized removable plug, with a volume of 100 ml, could be used to fill the extension to create a socket with a standard (small) distal void volume; in contrast, removal of the plug would create a socket with a large distal volume (an additional volume of 100 ml).

¹⁰ From the findings in Appendix A: Estimating the distal void volume between residuum and socket based on typical prosthetist's practice

The plug was designed in 3 parts (see *Figure 3.6*).

Figure 3.5 shows the geometry of the plugs.

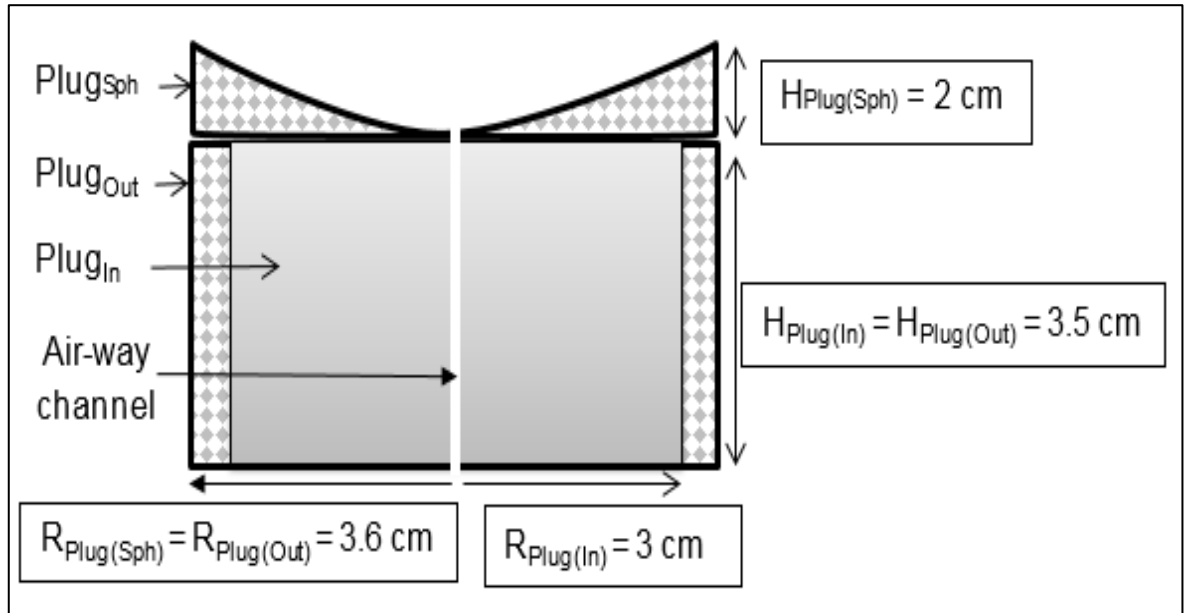


Figure 3.5: A schematic drawing, showing the geometry of the plugs (side view). During test-conditions, all plugs will be kept for small V_2 , while Plug_{In} will be removed to create large V_2 (additional 100 ml).

Figure 3.6 shows the plugs that will be used in the following main study to create small V_2 and large V_2 (additional 100 ml).

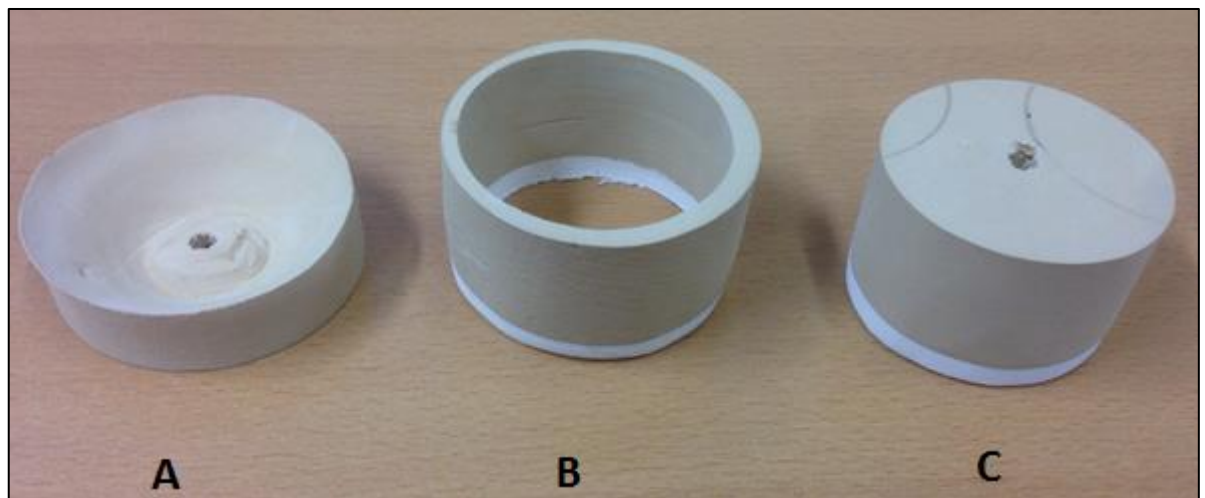


Figure 3.6: The 3 manufactured plugs: Spherical plug (A), inner plug (B), and outer plug (C).

Finally, a new test-socket was designed as shown in *Figure 3.7*.

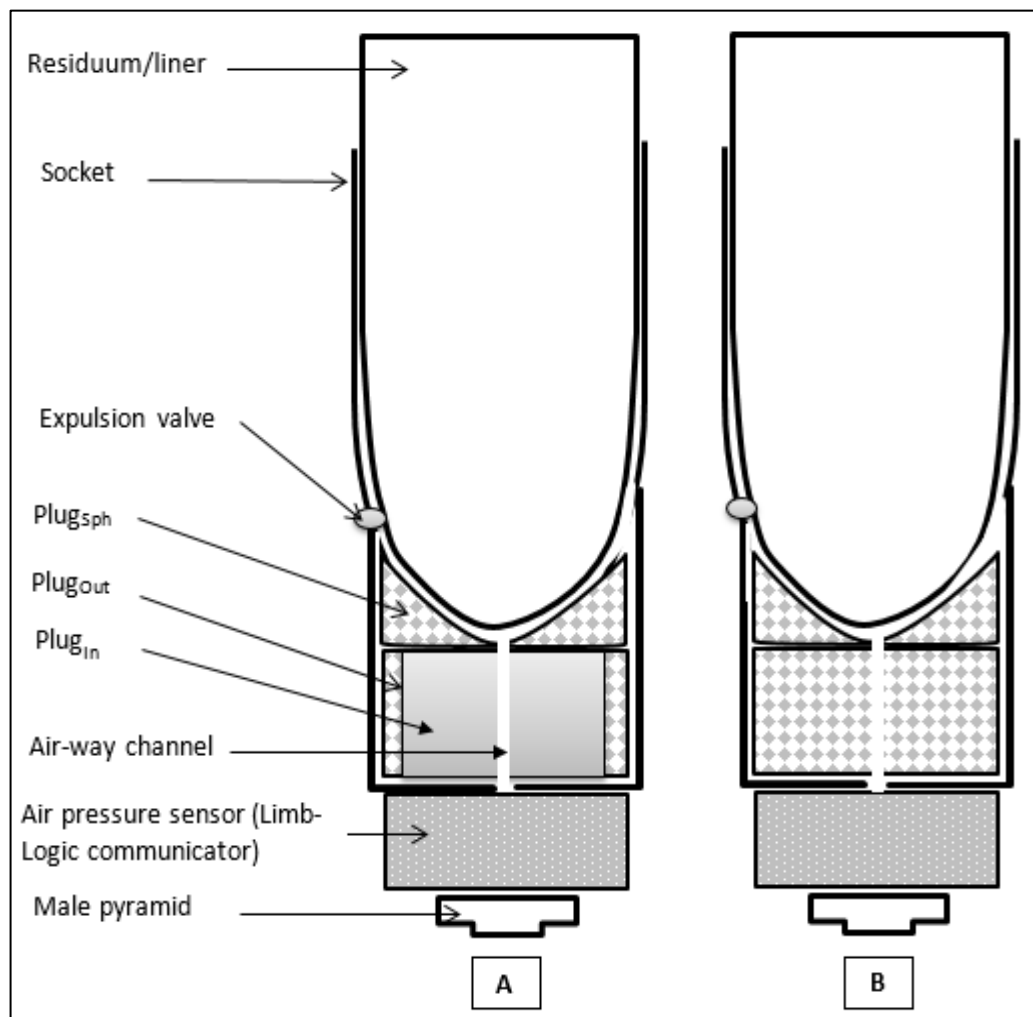


Figure 3.7: A schematic drawing of a new test-socket design, with small (A) and large (B) initial distal void volumes

3.4. Instrumented Trans-tibial Prosthesis (ITTP)

The ITTP was to be designed to:

1. Accommodate a suitable vacuum pump/pressure monitor at the distal end and;
2. Be sufficiently compact to allow for correctly aligned distal componentry, including an ankle and a foot.

The primary components of the ITTP were as follows; please also refer to *Figure 3.8*.

- 1) A urethane sleeve suspension: to prevent any air leakage through the socket's proximal brim;
- 2) A Seal-In liner¹¹: to create a passive vacuum-based system with the urethane sleeve suspension and the manual expulsion valve. This type of liner can fit intimately to the residuum and laser-based scanning can be employed to capture its geometry;
- 3) A test-socket with inner plugs: to create different distal void volumes across the test-conditions;
- 4) A Limb-Logic Communicator¹² (combined air pressure sensor and vacuum pump): to both measure (when in passive mode (i.e., SSSS)) and create (when active (i.e., VASS)) vacuum air pressure inside the test-socket;
- 5) A rotatable male pyramid¹³: to attach the test-socket to the pylon and align the ITTP to the prosthetic foot;
- 6) A pylon with two clamp adapters¹⁴: to adjust the ITTP length based on the subject's height. Note, these parts may be replaced with a double clamp adapter, if the subject has a long residuum, as shown in *Figure 3.9*.
- 7) A foot adapter¹⁵: to attach the prosthetic foot to the remainder of the prosthesis and;
- 8) A clinical standard Solid Ankle Cushion Foot (SACH foot)¹⁶. This foot type was selected as it is commonly used within clinical practice and was available in different sizes allowing testing consistency to be achieved among the participants.

¹¹ Ossur, Reykjavik, Iceland

¹² Ohio Willow Wood, Ohio, USA

¹³ Otto Bock, Duderstast, Germany

¹⁴ Otto Bock, Duderstast, Germany

¹⁵ Otto Bock, Duderstast, Germany

¹⁶ Otto Bock, Duderstast, Germany

Figure 3.8 shows the ITTP with its primary components.

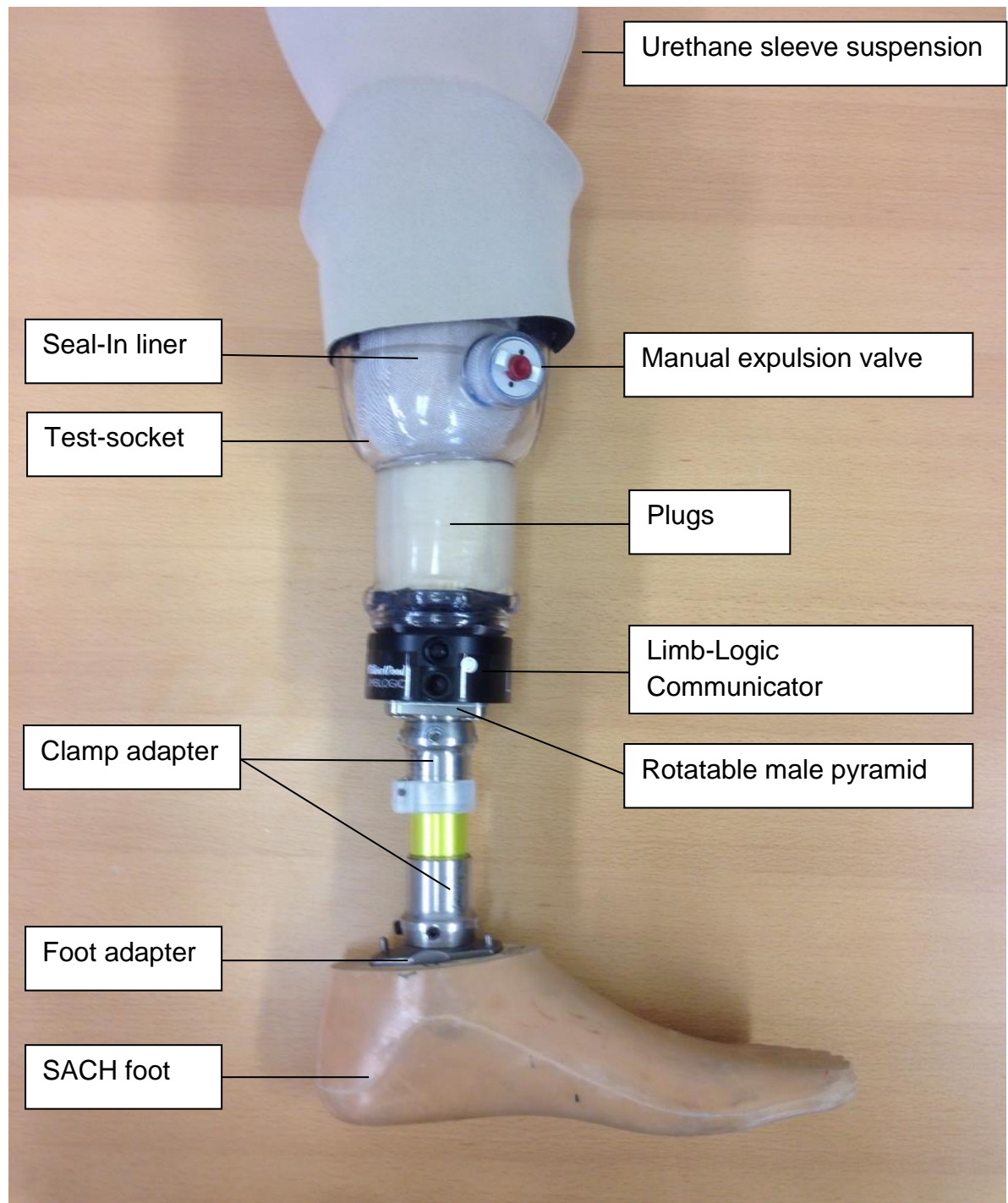


Figure 3.8: The main components of the Instrumented Trans-tibial Prosthesis (ITTP).

Figure 3.9 shows the ITTP with minimum residuum-ground clearance.

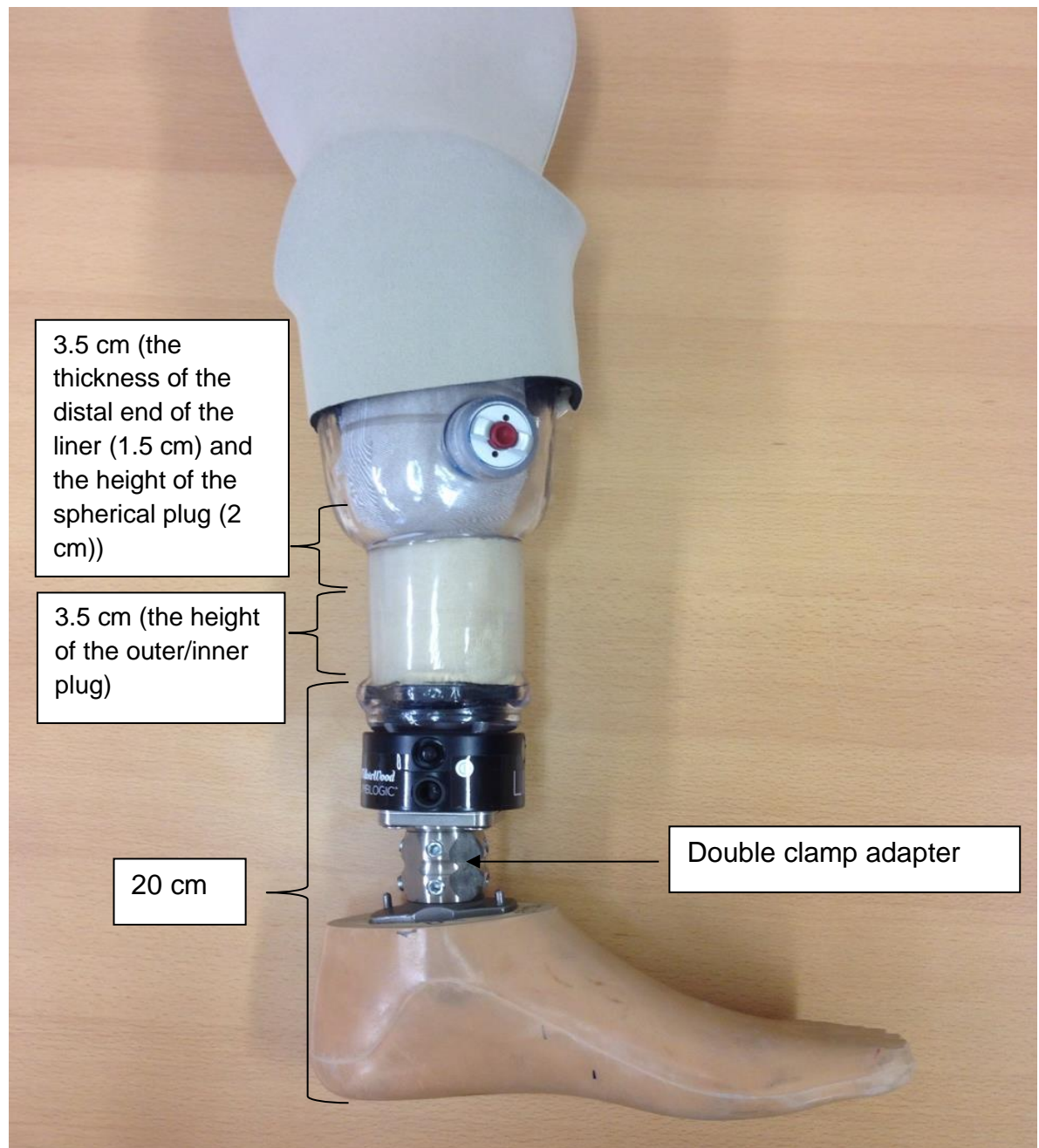


Figure 3.9: The main components of the Instrumented Trans-tibial Prosthesis (ITTP). The pylon with two clamp adapters was replaced with a double clamp adapter in order to estimate the minimum residuum-ground clearance (27 cm) that allow for full assembly of the ITTP.

3.5. Discussion

This chapter has presented the design of the ITTP required for this study. The major consideration at all times was the safety of the participants. Every effort was made to ensure that the socket and the ITTP was robust and fit for purpose.

The design and construction of the plugs allows the researcher to alter the distal void volumes in a simple, repeatable manner and hence, investigate the effect of this on residuum volume maintenance. The test-socket design, incorporating the plugs, is illustrated in *Figure 3.7*, and is of a similar design to a standard prosthesis, albeit with a clear thermoplastic socket. The length of the prosthesis is increased by the addition of the plugs however, meaning that the recruitment criteria should include a minimum residuum-ground clearance (27 cm) to allow for full assembly of the ITTP (*Figure 3.9*).

3.6. Conclusions

A larger distal void volume may reduce the reduction in residuum volume seen when using standard socket designs by decreasing the in-socket air pressure changes. To explore this issue, a prosthesis with a configurable distal void volume was designed. The ITTP designed and shown here can provide the means to achieve this goal, and will be used in the main study to collect the related data (*Figure 3.8*). A Limb-Logic Communicator will be employed as a VASS. At all stages, comfort and socket fit will be assessed to ensure that all data is compatible with normal usage.

Chapter 4: Within-day repeatability of residuum volume measurement and gait parameters of traumatic trans-tibial amputees

4.1. Introduction

Short-term fluctuations in the residuum volume of lower limb amputees is a common clinical problem, the causes of which remain relatively poorly understood. Factors believed to influence these changes include the aetiology of limb loss (3, 50, 75), physical activity (50, 80, 81) and the design of the prosthetic suspension system (1-3). Residuum Volume Fluctuations (RVFs) may lead to a number of problems related to socket fit (50). For example, an increase in residuum volume can restrict blood circulation in the residuum (65). A more common problem is the reduction in residuum volume which often occurs over periods of upright mobility (3, 50), leading to a loosening of socket fit. During gait, a loose fitting socket will lead to pistoning (relative movement between the residuum and socket), which may in turn lead to gait asymmetry (21), residuum pain (46), and in the longer term damage to tissue (51).

Actively-driven, low pressure prosthetic suspension (active) systems have shown promise as a means of reducing short-term fluctuations in residuum volume (1-3). For example, Board et al (2001) (2) showed that residuum volume increased by 3.7% (-1.6% to 8.5%) and decreased by 6.5% (-11.3% to -1.7%), compared to baseline volume (V_{baseline}), following 30 minutes of walking with Active-Assisted Suspension System (VASS) and Suction Socket Suspension System (SSSS) respectively (2). Studies such as these are reliant on accurate measurement instruments and associated protocols for measuring residuum volume.

In addition, changes to residuum volume are likely to impact on gait, due to compensatory movements needed to accommodate pistoning.

In order to have confidence in the results of the following main study, it was necessary to carry out a repeatability study on the two key measurement

techniques: 1) Measurement of residuum volume and; 2) Measurement of gait kinematics and Ground Reaction Forces (GRFs).

Various measurement instruments have been used to measure residuum volume, including multiple circumferential measurements using a tape measure (66), water displacement method (67), casting method combined with the water displacement technique (68), ultrasound imaging (69), radiological imaging (Computerised Tomography (CT) and Magnetic Resonance Imaging (MRI)) (70, 71), and 3-Dimensional (3D) optical surface scanning (73). In addition, a bio-impedance-based system (72) has been used to provide a measure which is proportional to fluid (not residuum) volume and hence is not comparable with the other systems. However, circumferential measurements and casting methods are inherently inaccurate, CT scanning involves exposure to ionising radiation and MRI is limited due to the cost of accessing the equipment.

The laser-based scanner systems now commonly used to capture residuum geometry (1) are portable, fast to use and safe. However, most of the repeatability studies of these systems have been conducted using regular-shaped objects (82-84) or models of a residuum (82, 83, 85, 86) and have not considered other factors that may introduce errors. These factors may include boundary definitions for residuum geometry, residuum movement and associated soft tissue deformation, or joint contractures which may limit the scanning process, each of which may have led to an over-estimation of measurement repeatability in the earlier studies.

Only De Boer-Wilzing et al (2011) (54) compared the repeatability of four different techniques (water displacement, 3D optical scanner¹⁷, volume estimation based on circumference measurements, and laser-based scanner system¹⁸) in amputee subjects. Residuum volume, defined as the volume distal to the knee joint was measured in 26 subjects on 2 visits, each consisting of 2 sessions. In each session, 2 observers measured the residuum volume for each participant using the four different techniques. 8 minutes of settling time was provided between doffing the socket and the first measurement. The authors reported repeatability coefficients

¹⁷ Design TT, Otto Bock, Germany

¹⁸ Omega Tracer, Ohio WillowWood, USA

ranging from 129mL (laser-based scanner) and 158mL (3D optical scanner). However, the authors did not report the absolute residuum volumes making the errors difficult to both interpret and compare to other studies (1-3).

Several factors may affect the repeatability with which gait parameters can be measured. The position of body-mounted retro-reflective markers and consequent definition of local reference frames can be subject to user error (87) and/or skin-marker movements during walking (87). Finally, step-to-step variations within and between participants across test-conditions will also contribute to variation in outcomes (88).

Only an old study conducted by Zahedi et al (1987) (88) assessed the repeatability of gait kinematics and kinetics of lower limb amputees. However, the technology used has now been superseded.

The aims of this study were to assess the within-day test-retest repeatability of:

1. Residuum volume measurement in amputee participants using a laser-based scanner system and;
2. Gait kinematics and Ground Reaction Forces (GRFs).

4.2. Methods

This study involved 5 participants with unilateral trans-tibial amputation, visiting the University of Salford on one occasion. The data for this study were collected using the following equipment:

- OMEGA Tracer¹⁹ (Laser-based scanner system): to measure the residuum volume;
- Vicon Motion Capture System²⁰ (Optical motion capture system): to collect the kinematics data and;
- Kistler Force Plates²¹ (Force plates): to collect the GRFs data.

¹⁹ Ohio Willow Wood, Ohio, USA

²⁰ Vicon, Oxford Metrics, Oxford, UK

²¹ Kistler, Kistler Instruments Ltd, Alton, UK

4.2.1. Participants and recruitment

Following ethical approval from the University of Salford (Appendix B.1), five participants with unilateral trans-tibial amputation (*Table 4.1*) satisfying the following criteria were recruited from the pool of professional amputees that participate in Salford's undergraduate Prosthetics and Orthotics (P&O) programme:

Inclusion criteria:

- Unilateral trans-tibial amputation level;
- More than one-year's experience of ambulation with a prosthesis;
- Over 18 years old;
- Able to walk continuously and comfortably for at least 10 meters during each walking trial;
- Able to travel to the University of Salford and;
- Able to understand both written and spoken English.

The exclusion criteria were:

- Bilateral lower limb amputation and/or;
- Upper limb amputation (for safety during the trials).

Table 4.1 provides details of the recruited participants.

Table 4.1: Participants' characteristics.

Participant	Gender	Age (Years)	Height (m)	Mass (Kg)	Time since amputation (Years)	Cause of amputation	Amputation side	Mobility grade *
1	Male	64	1.85	84	42	Trauma	Right	K3
2	Male	56	1.8	76	14	Trauma	Left	K4
3	Male	48	1.79	90	11	Trauma	Right	K4
4	Male	67	1.8	105	32	Trauma	Left	K3
5	Male	78	1.7	75	17	Trauma	Left	K3
Mean		62.6	1.8	86	23.2			
±		±	±	±	±			
SD		11.3	0.1	12.3	13.3			

(*) K-levels refer to the Medicare Functional Classification Levels (MFCLs) (89). K3 level corresponds to community ambulation; K4 corresponds to recreationally active.

4.2.2. Experimental procedures

One visit to the University of Salford was required for each participant to complete the study (2 hours 30 minutes approximately in duration). Data were collected in the gait lab of the Brian Blatchford Building, as explained in *Figure 4.3*.

Descriptive information (gender, age, height, mass, time since amputation, cause of amputation, amputation side, and mobility grade) were collected before testing began. All measurements were taken with the prosthesis donned and, apart from mass and height measurement, all measures were taken while the participants were sitting down. The participant then removed the socket while keeping the liner donned. A number of reflective targets, were placed on the silicone liner according

to manufacturer guidelines²², (see *Figure 4.1*). These were used later to capture the residuum volume and to define the upper bound of the residuum.



Figure 4.1: Reflective targets of the OMEGA tracer system placed on a silicon liner (74).

The participant then re-donned his socket and 42 spherical retro-reflective markers were attached to the participant's pelvis and lower limbs, either singularly onto the skin, or within a cluster²³ (see *Figure 4.2*). These markers were attached according to the Calibrated Anatomical System Technique (CAST) established by Cappozzo (87). The CAST technique, a) limits the impact of skin-marker artefacts (87) and; b) allows for reconstruction of the relative 3D position and 3D orientation of neighbouring body segments (87). Following the static trial, the participant was invited to walk 20 times along the length of laboratory (~ 175 m) at self-selected speed. Markers were then removed, replaced and the participant repeated the 20 walks. The participant then sat down, removed the socket while keeping the liner donned, and the volume of their residuum plus liner was measured using the laser-based scanner system. Measurements of residuum volume were then repeated four

²² Ohio Willow Wood, Ohio, USA

²³ A rigid polyethylene plate with four retro-reflective markers mounted on it

more times over 20 minutes. Finally, the markers were removed and the participant re-donned his prosthesis.

Kinematic data were collected using Vicon Motion Capture System at a sampling frequency of 100 Hz. Four Kistler Force Plates were used to collect the GRFs at a sampling frequency of 1000 Hz.

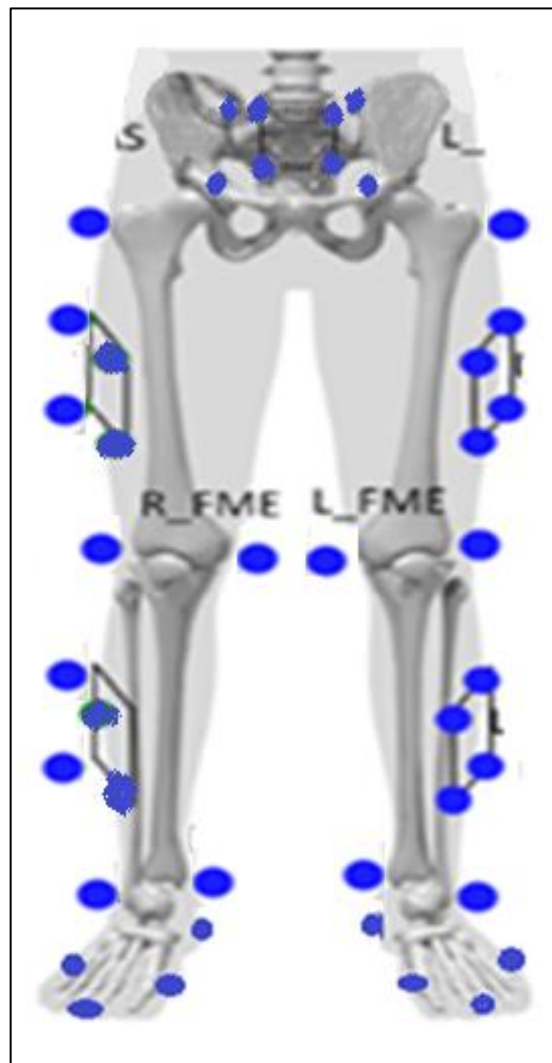


Figure 4.2: Locations of the spherical retro-reflective markers on the participant, using a CAST model.

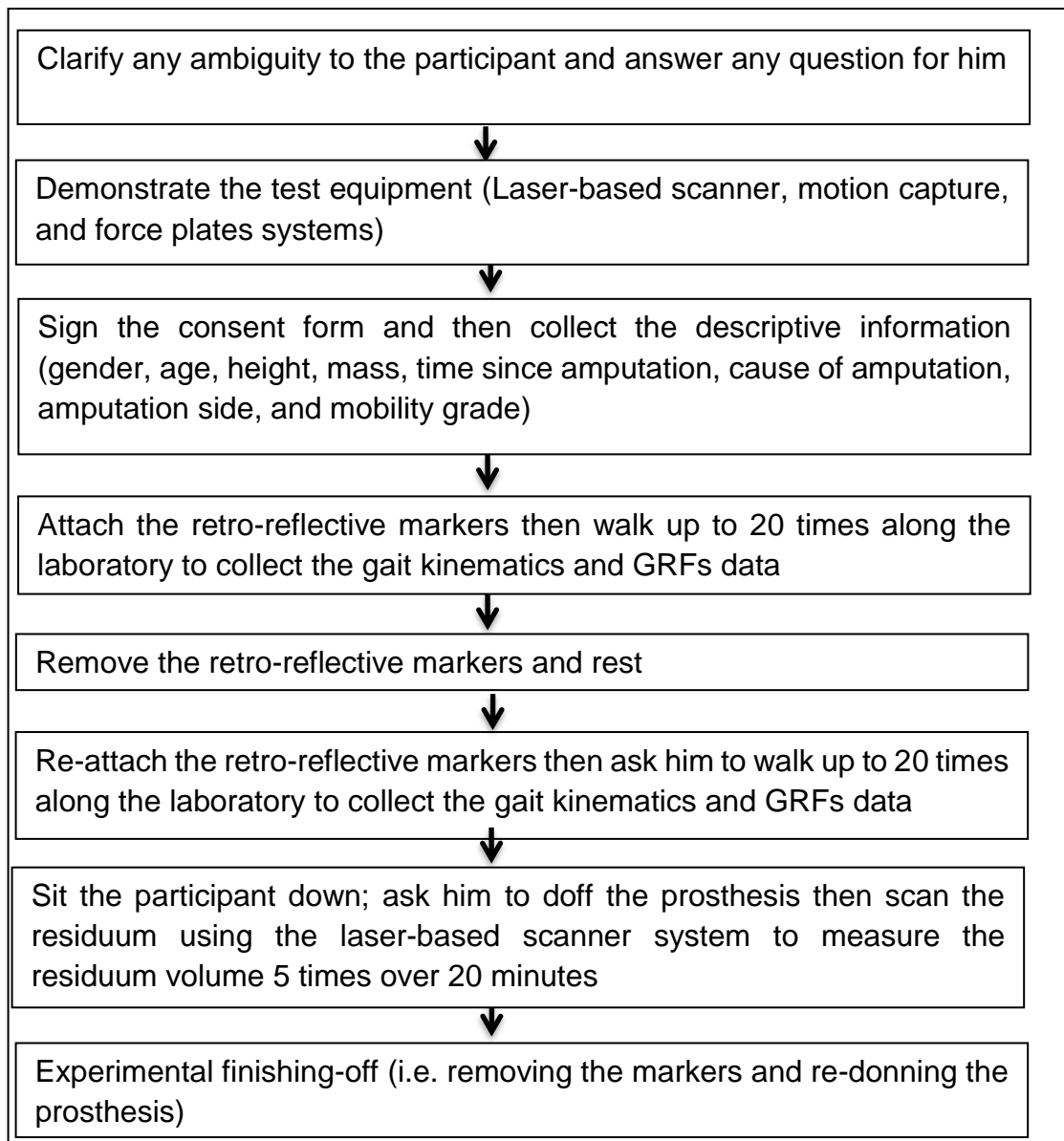


Figure 4.3: The schedule of testing during a single visit.

4.2.3. Data analysis

The volume of interest in the 3D model created in OMEGA Tracer software was considered to lie distal to a user-defined plane. The plane was calculated in the software using the target placed on the distal end of the patella and a line connecting two reflective targets attached on the lateral aspect of the residuum at the proximal and distal ends. The process of data analysis using the OMEGA system is detailed in Appendix C: Measuring the residuum volume using a laser-based scanner system.

Gait kinematics and GRFs data were analysed using Vicon Nexus Software²⁴ and Visual 3D (V3D) software²⁵. The CAST model was used for reconstruction of the relative 3D position and 3D orientation of neighbouring body segments (87). Data were digitally filtered for high frequency noise by applying a 4th order low pass Butterworth filter with a cut-off frequency of 6Hz for kinematics and 25Hz for GRFs data (90). The kinematics and GRFs data were normalised to the gait cycle and stance phase respectively, from 0% to 100%. The Range of Motion (RoM) of the selected gait kinematics and the peaks of GRFs were identified in each accepted trial for each participant, and averages calculated. The gait parameters studied reflected those previously reported to reflect likely gait deviations to compensate for pistoning. Thus, the following gait parameters were investigated:

1) Gait kinematics:

- RoM of the frontal pelvic obliquity angle on the prosthetic limb side (56, 57);
- RoM of the sagittal prosthetic hip and knee joints angles (57) and;
- RoM of the sagittal sound ankle joint angle (58).

2) GRFs of the prosthetic limb. Pistoning may decrease the prosthesis users confidence and hence, decrease the loading onto the prosthesis during the stance phase. Pistoning might also lead to the prosthesis users managing this problem through the compensatory strategies described above.

A trial was accepted for analysis if the speed was within $\pm 5\%$ of the average speed, and one complete step was made on one of the force plates.

4.2.4. Statistical analysis

Results of residuum volume and gait kinematics and GRFs were tested as follows:

²⁴ Vicon, Oxford Metrics, Oxford, UK

²⁵ C-motion Incorporation, Germantown, USA

4.2.4.1. Residuum volume

The repeatability of residuum volume measurements was estimated using the Coefficient of Variation (CV) and expressed as a percentage (formula 4) for each participant. The mean of all of the participants' results were then calculated.

$$CV = \frac{SD}{Mean} * 100\% \quad (4)$$

Where, SD and mean are the standard deviation and mean of the residuum volume measurements for each participant across the 5 scans.

The percentage change in residuum volume relative to the first scan after doffing the prosthesis was calculated as follows.

$$\Delta \text{Residuum volume} = \frac{V_t - V_0}{V_0} * 100\% \quad (5)$$

Where, v_0 and v_t are the residuum volumes at time point zero and at t minutes after doffing the prosthesis, respectively.

4.2.4.2. Gait kinematics and GRFs

Assessing the test-retest repeatability of gait kinematics and GRFs was carried out using the Statistical Package for Social Sciences (SPSS) Software²⁶. The Intra-class Correlation Coefficient (ICC), was calculated as the metric to classify the consistency of results (relative reliability) between test and retest. The ICC classification was considered (excellent (> 0.75), fair to good (0.4 to 0.75), and poor (< 0.4)), based on Fleiss (1986) (91).

The Standard Error of Measurement (SEM) was then calculated to find the variation within-participants (absolute reliability) (92) using formula (6).

$$SEM = \sqrt{\frac{\sum SD^2}{n}} \quad (6)$$

²⁶ IBM SPSS Statistics 20, SPSS Incorporation, Chicago, USA

Where, SD is the standard deviation between the means of the two sessions of each participant for each variable, and n is the number of participants.

Finally, the Minimal Detectable Differences (MDD) was calculated using formula (7). The aim of addressing the MDD was to define the minimum amount of changes in the variables of the future study that must be achieved to reflect true differences due to interventions, not due to error, such as markers placements (93).

$$MDD = 1.96 * SEM * \sqrt{2} \quad (7)$$

Where, SEM is the standard error of measurement.

4.3. Results

The results of residuum volume measurements and gait kinematics and GRFs are addressed in the following sections.

4.3.1. Residuum volume

Table 4.2 illustrates the results of repeatability of residuum volume measurements (ml) using the Coefficient of Variation (CV).

Table 4.2: Results of repeatability of residuum volume measurements (ml) using the Coefficient of Variation (CV).

Time	Pt1	Pt2	Pt3	Pt4	Pt5
0	918	920	1181	1150	1633
5	904	916	1198	1186	1626
10	914	921	1186	1189	1634
15	912	917	1199	1195	1629
20	918	922	1180	1207	1617
Mean (ml)	913.2	919.2	1188.8	1185.4	1627.8
SD (ml)	5.8	2.6	9.1	21.4	6.8
CV %	0.6	0.3	0.8	1.8	0.4

Figure 4.4 shows the percentage of residuum volume changes relative to first measurement. Only, Pt4 complained about pistoning after conducted the walking trials.

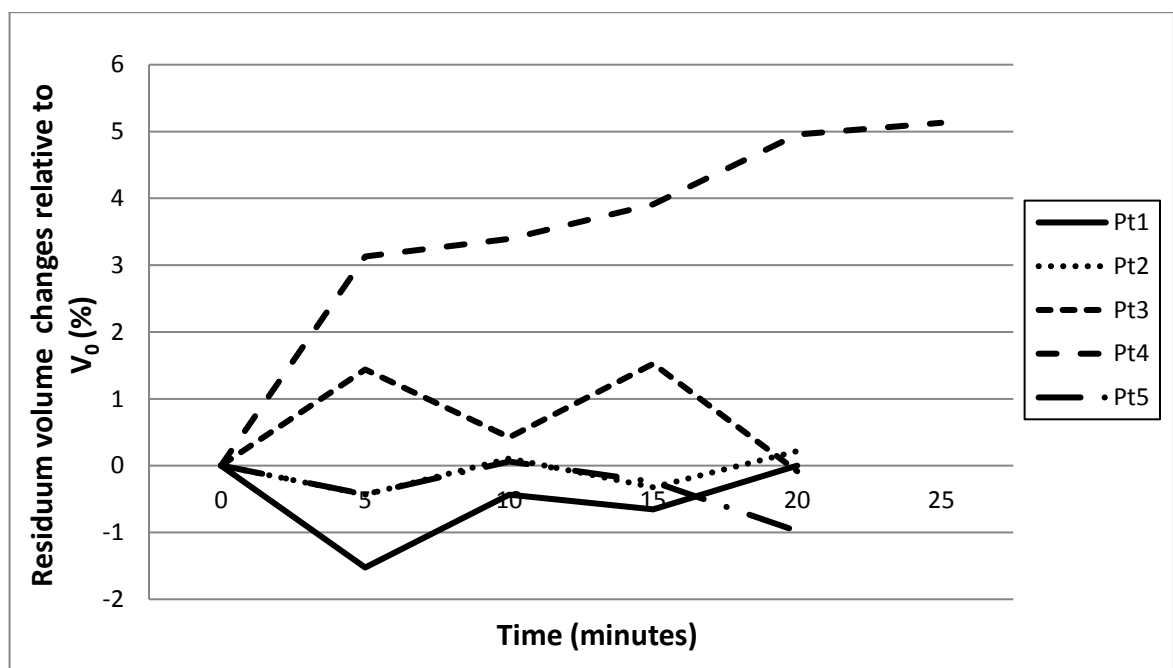


Figure 4.4: Residuum volume changes relative to the first measurement (V_0) over 20 minutes for all participants. For Pt4, the residuum volume changes were measured over 25 minutes due to his self-reported pistoning during the session.

4.3.2. Gait kinematics and GRFs

Figure 4.5 shows an example of frontal pelvic obliquity on the prosthetic limb side.

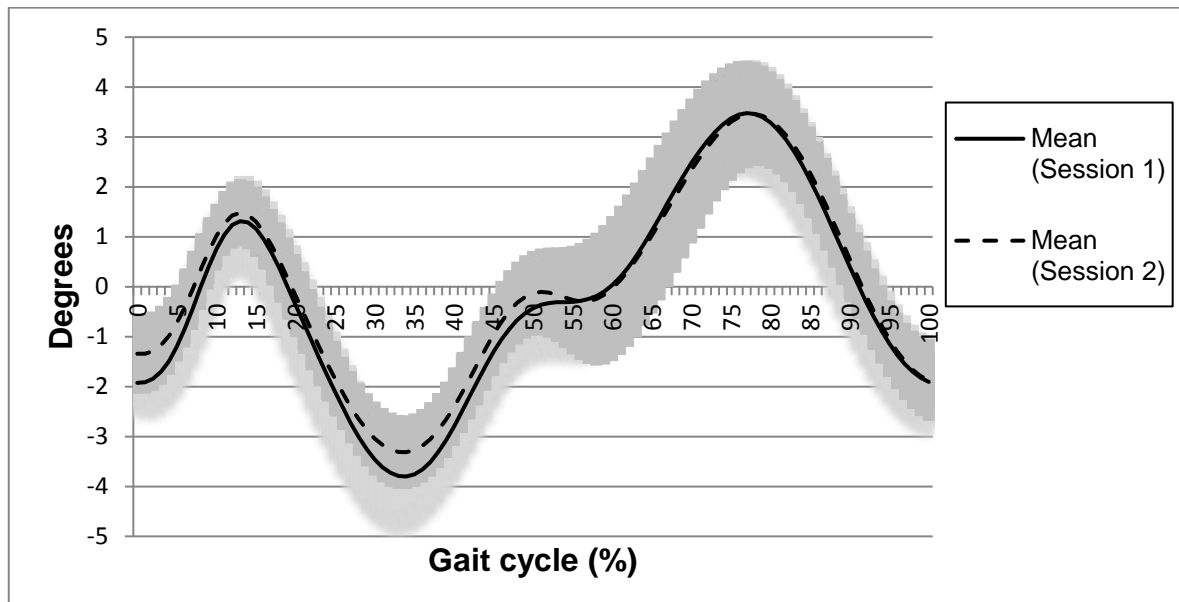


Figure 4.5: The mean \pm SD of frontal pelvic obliquity on the prosthetic limb side during walking, for participant 1. (SD with light and dark outlines for Session 1 and Session 2 respectively).

Figure 4.6 shows the averaged frontal pelvic obliquity on the prosthetic limb side.

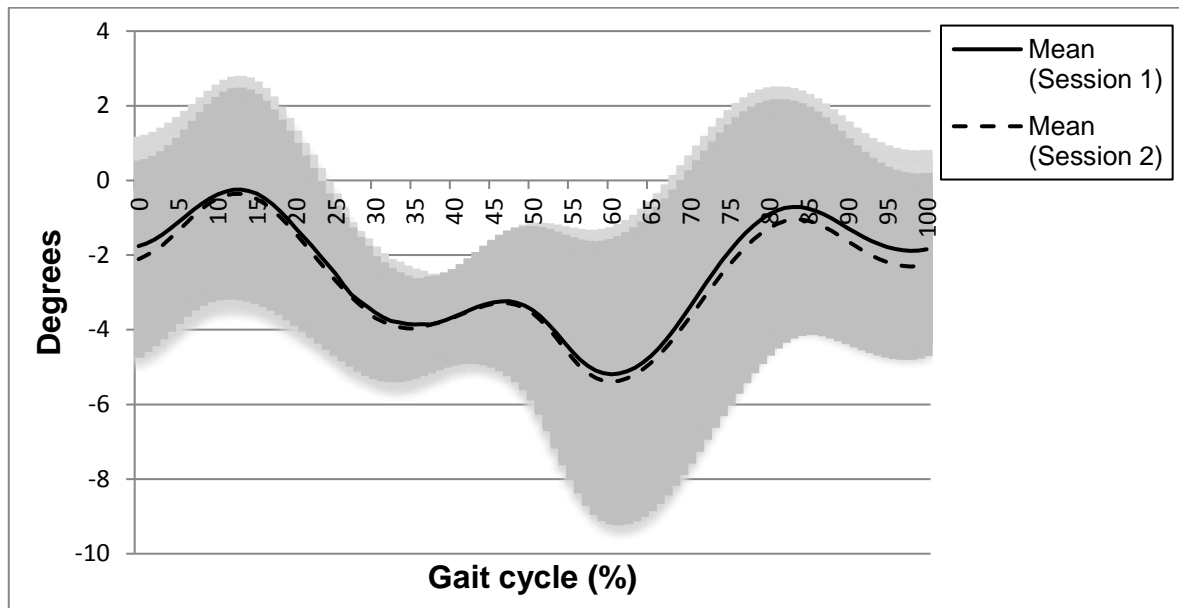


Figure 4.6: The mean \pm SD of frontal pelvic obliquity on the prosthetic limb side during walking, for all the participants. (SD with light and dark outlines for Session 1 and Session 2 respectively).

Figure 4.7 shows an example of sagittal prosthetic hip joint kinematic.

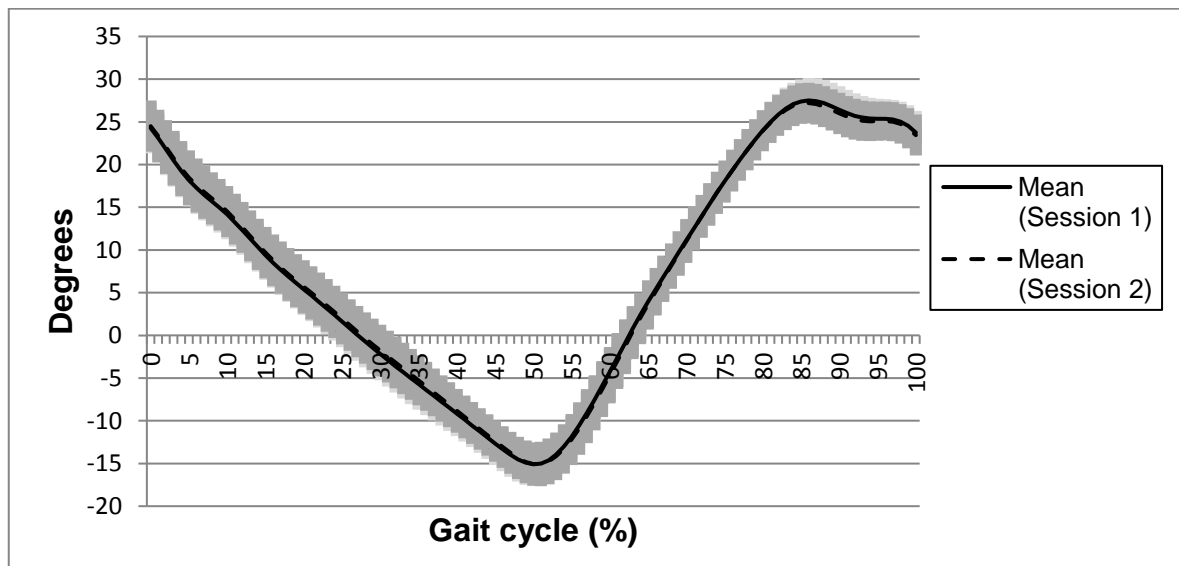


Figure 4.7: The mean \pm SD of sagittal hip joint (prosthetic-side) kinematic during walking, for participant 1. (SD with light and dark outlines for Session 1 and Session 2 respectively).

Figure 4.8 shows the averaged sagittal prosthetic hip joint kinematic.

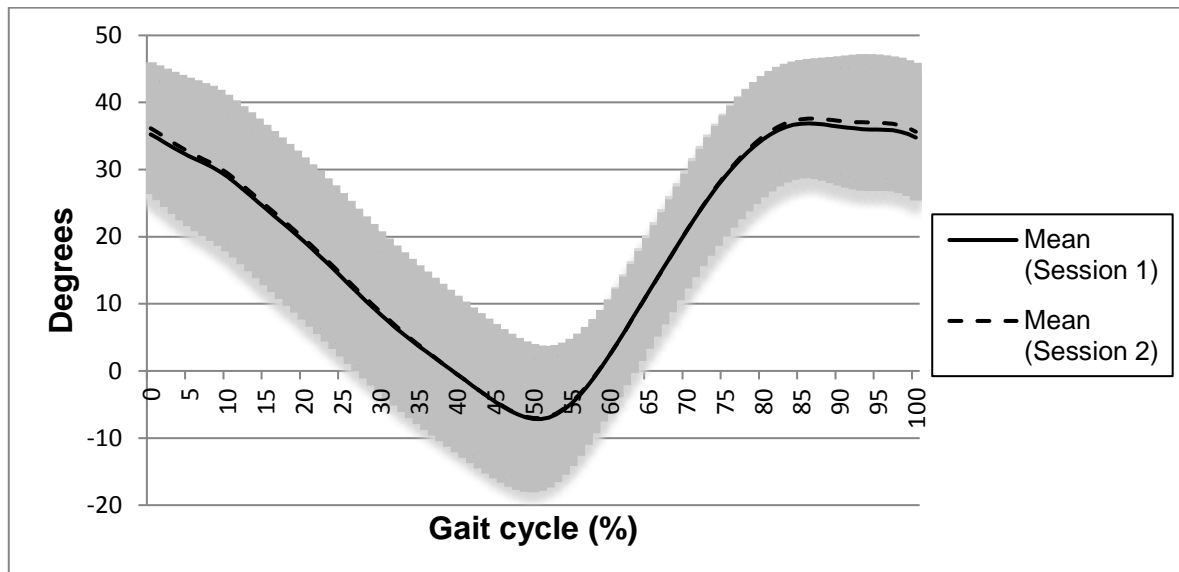


Figure 4.8: The mean \pm SD of sagittal hip joint (prosthetic-side) kinematic during walking, for all the participants. (SD with light and dark outlines for Session 1 and Session 2 respectively).

Figure 4.9 shows an example of sagittal prosthetic knee joint kinematic.

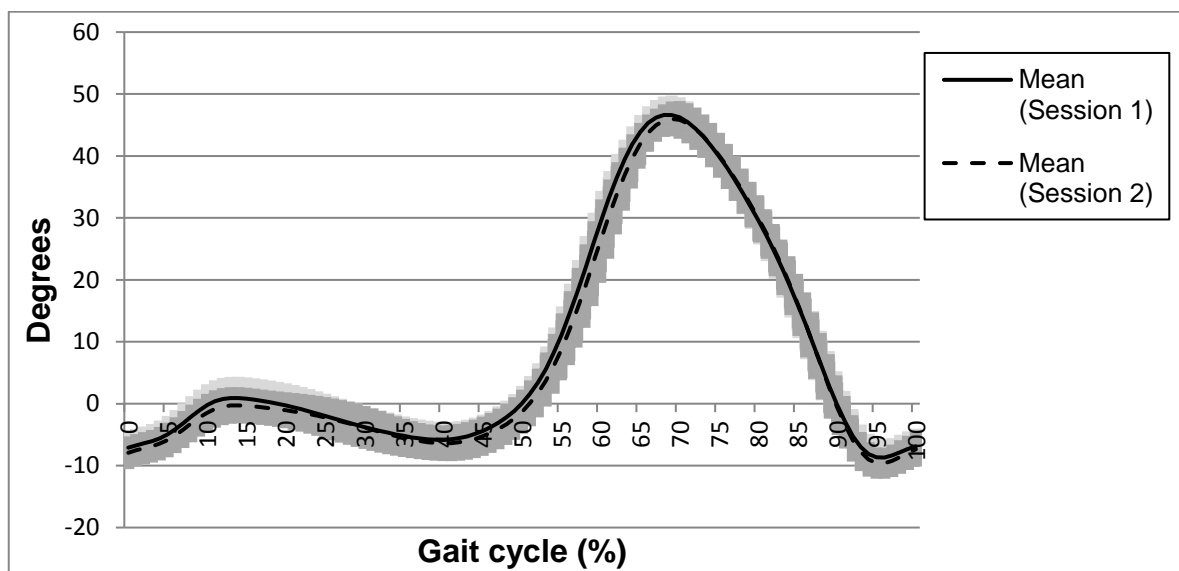


Figure 4.9: The mean \pm SD of sagittal knee joint (prosthetic-side) kinematic during walking, for participant 1. (SD with light and dark outlines for Session 1 and Session 2 respectively).

Figure 4.10 shows the averaged sagittal prosthetic knee joint kinematic.

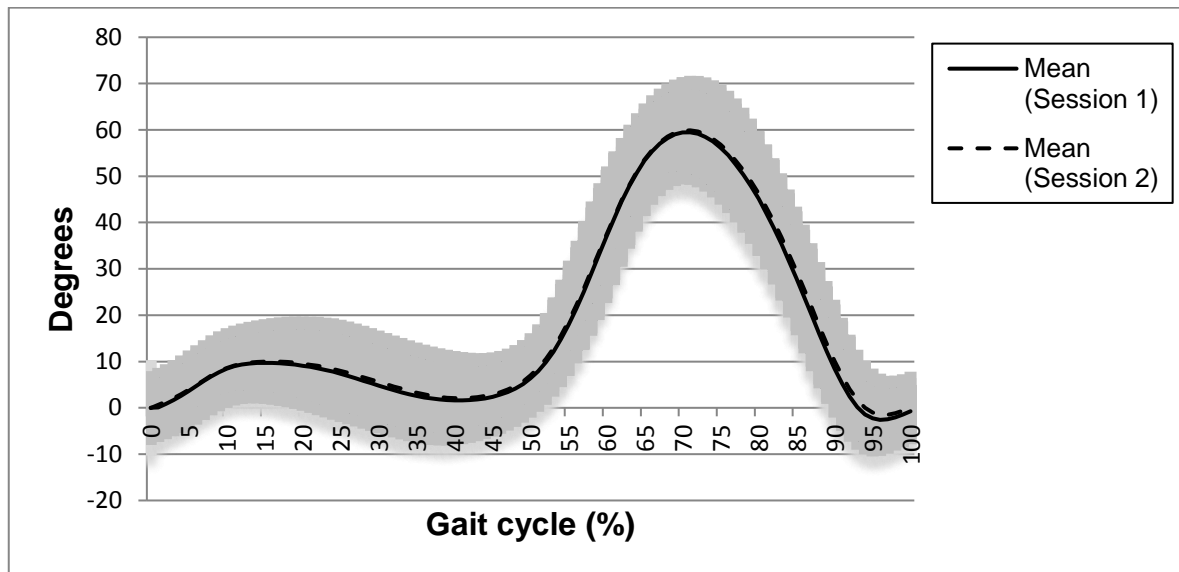


Figure 4.10: The mean \pm SD of sagittal knee joint (prosthetic-side) kinematic during walking, for all the participants. (SD with light and dark outlines for Session 1 and Session 2 respectively).

Figure 4.11 shows an example of sagittal sound ankle joint kinematic.

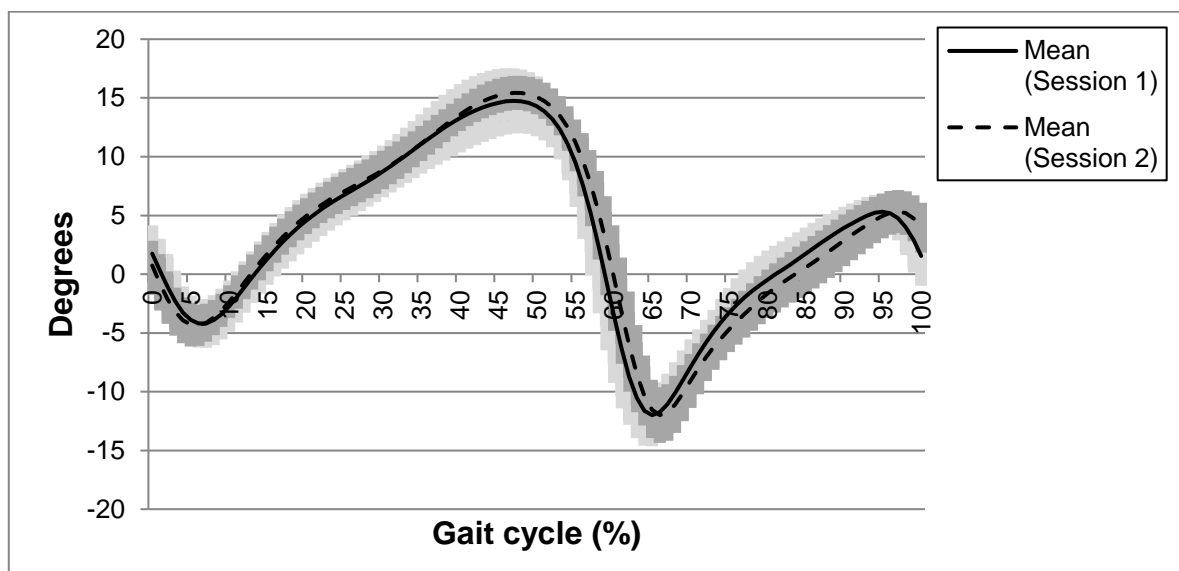


Figure 4.11: The mean \pm SD of sagittal ankle joint (sound-side) kinematic during walking, for participant 1. (SD with light and dark outlines for Session 1 and Session 2 respectively).

Figure 4.12 shows the averaged sagittal sound ankle joint kinematic.

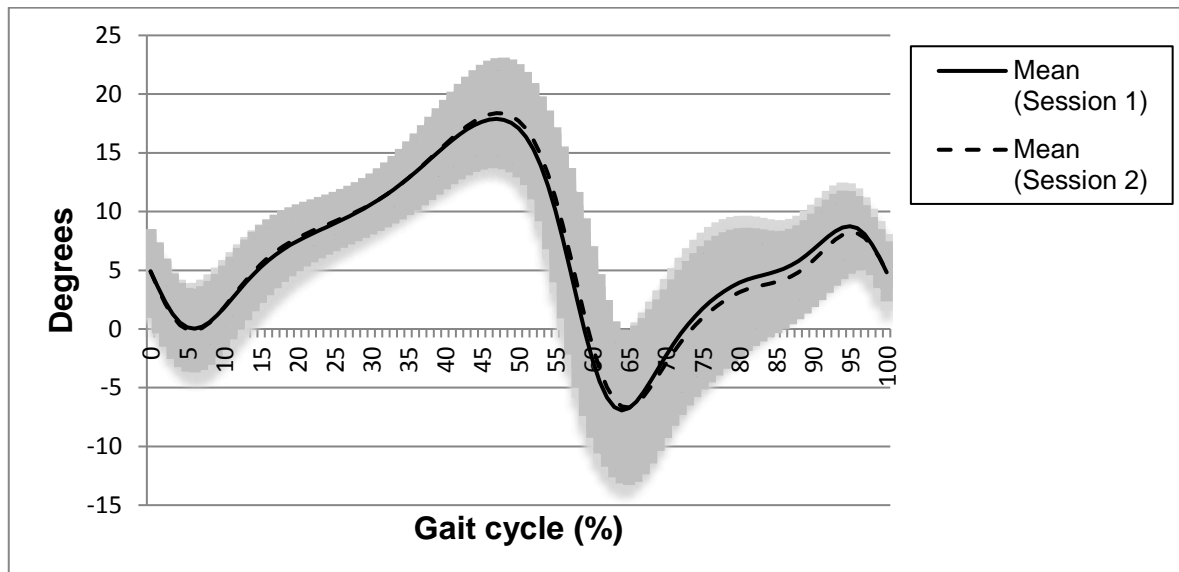


Figure 4.12: The mean \pm SD of sagittal ankle joint (sound-side) kinematic during walking, for all the participants. (SD with light and dark outlines for Session 1 and Session 2 respectively).

Figure 4.13 shows the averaged Vertical GRFs of the prosthetic limb.

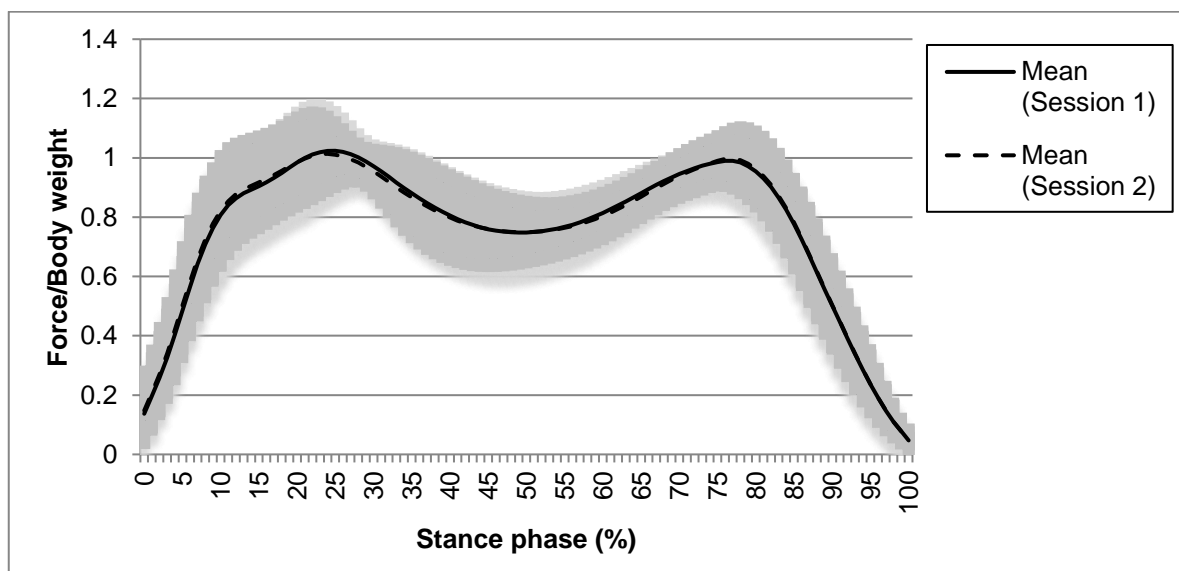


Figure 4.13: The mean \pm SD of Vertical GRFs of the prosthetic limb during the stance phase, for all the participants. (SD with light and dark outlines for Session 1 and Session 2 respectively).

Figure 4.14 shows the averaged Anterior-Posterior GRFs of the prosthetic limb.

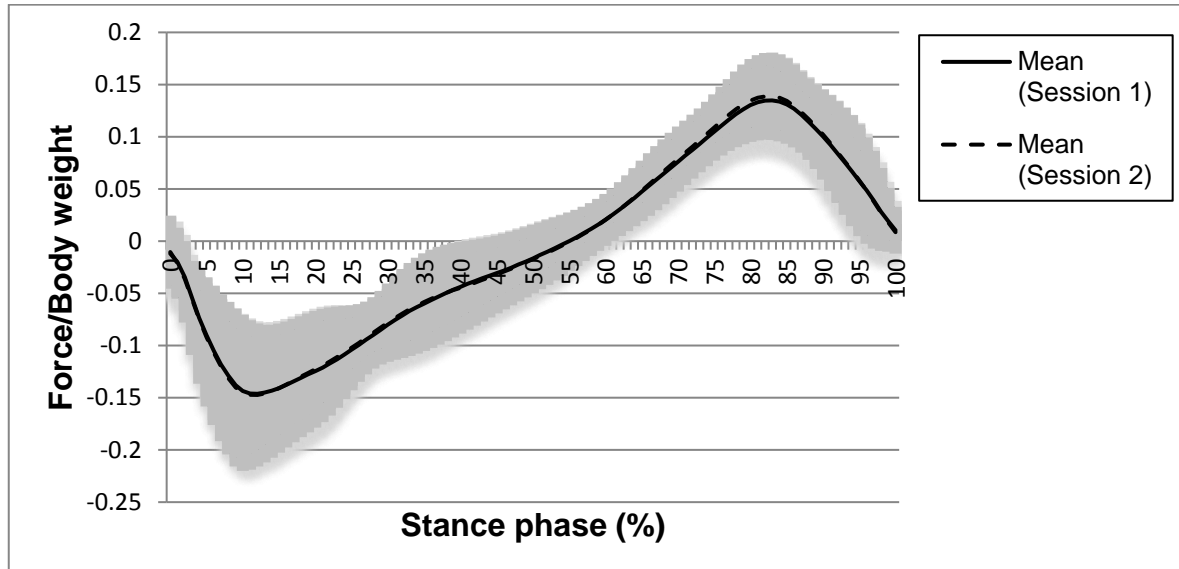


Figure 4.14: The mean \pm SD of Anterior-Posterior GRFs of the prosthetic limb during the stance phase, for all the participants. (SD with light and dark outlines for Session 1 and Session 2 respectively).

Figure 4.15 shows the averaged Medial-Lateral GRFs of the prosthetic limb.

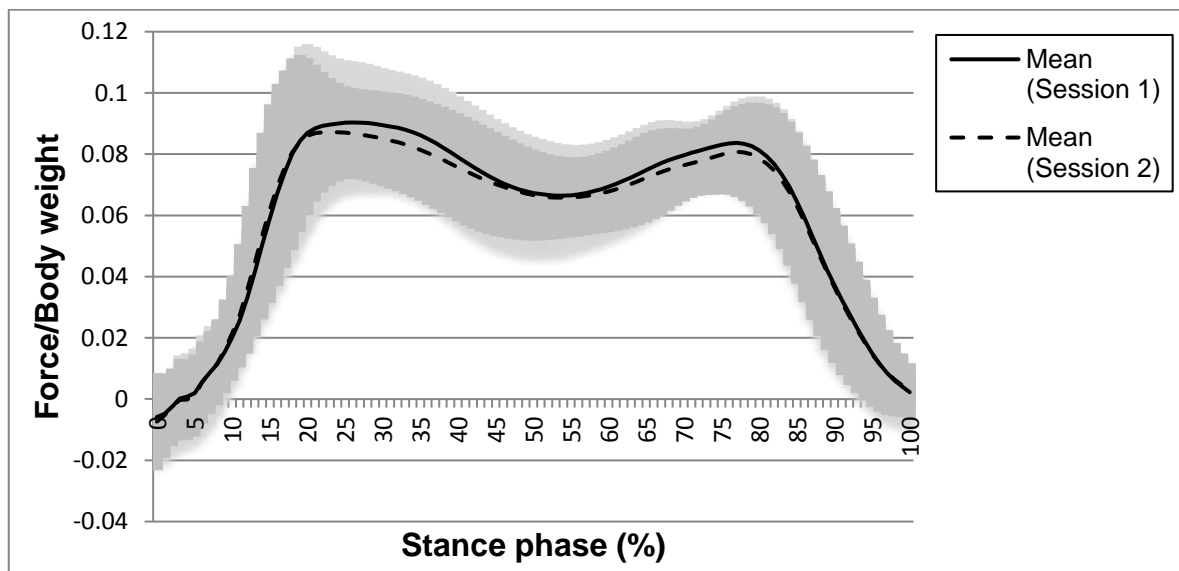


Figure 4.15: The mean \pm SD of Medial-Lateral GRFs of the prosthetic limb during the stance phase, for all the participants. (SD with light and dark outlines for Session 1 and Session 2 respectively).

Table 4.3 illustrates the results of within-day repeatability of gait parameters of trans-tibial amputee participants.

Table 4.3: Reliability of gait kinematics and GRFs during walking, for all the participants.

Prosthetic limb kinematic variables	Mean \pm SD (Degrees)	ICC (95% Confidence Interval (CI))	SEM (Degrees)	MDD (Degrees)
RoM of the frontal pelvic obliquity angle on the prosthetic limb side	6.4 \pm 1.7	0.99 (0.95 to 1.0)	0.2	0.5
RoM of the sagittal prosthetic hip joint angle	45.8 \pm 4.2	0.97 (0.80 to 1.0)	1.0	2.7
RoM of the sagittal prosthetic knee joint angle	64.3 \pm 8.2	1.0 (0.96 to 1.0)	0.8	2.3
Sound limb kinematic variable	Mean \pm SD (Degrees)	ICC (95% CI)	SEM (Degrees)	MDD (Degrees)
RoM of the sagittal sound ankle joint angle	26.0 \pm 5.7	0.99 (0.94 to 1.0)	0.7	2.1
Prosthetic limb GRFs	Mean \pm SD (* BW)	ICC (95% CI)	SEM (* BW)	MDD (* BW)
First peak of Vertical GRFs	1.07 \pm 0.08	0.97 (0.73 to 1.0)	0.02	0.05
Second peak of Vertical GRFs	1.02 \pm 0.05	0.97 (0.71 to 1.0)	0.01	0.02
Peak of Anterior GRFs	0.14 \pm 0.03	0.99 (0.95 to 1.0)	0.00	0.01
Peak of Posterior GRFs	0.16 \pm 0.05	1.0 (0.96 to 1.0)	0.00	0.01
Peak of Medial GRFs	0.10 \pm 0.02	0.93 (0.17 to 0.99)	0.01	0.02
Peak of Lateral GRFs	0.01 \pm 0.01	1.0 (1.0)	0.00	0.00

4.4. Discussion

This repeatability study has carried out prior to a subsequent larger study which has looked at a new method for reducing the reduction in residuum volume seen by many amputees. As the main study needs to measure both residuum volume and gait kinematics and GRFs; this study has demonstrated a within-day test-retest repeatability of these measurements on 5 traumatic trans-tibial amputees.

The discussion and conclusion of the main outcomes will be explained in the following section.

4.4.1. Residuum volume

The methods used to measure residuum volume showed a high degree of repeatability (*Table 4.2*). The mean CV after doffing the socket was $\approx 0.8\%$. This level of repeatability is encouraging, given the reported range of RVFs in the literature (1-3). It suggests that, for the single rater, by following the procedure described above with care highly repeatable measurements are possible.

Participant 4 was the only participant to report a loosening of his socket fit and consequent pistoning during gait. This observation is consistent with the data on residuum volume (*Figure 4.4*). Over the 25 minute measurement period the steepest rate of change of volume occurred during the 5 minutes immediately following doffing of the prosthesis. This observation is consistent with the results reported by Zachariah et al (2004) (64). However, as an increase in residuum volume beyond 20 minutes after doffing the socket has been reported in isolated subjects previously (Zachariah et al (2004) (64)), the suggested 4.3 minutes settling time proposed by Sanders et al (2012) (77) may be too short to reach a relatively stable residuum (fluid) volume. Therefore, we would recommend further studies to explore the length of recovery time required.

In conclusion, the within-day repeatability of residuum volume measurement was excellent ($CV < 1\%$). This finding supports the use of the laser-based scanner system used here in future studies in the area. In one participant, even after 25 minutes of rest following doffing of the socket (but not the liner), it appeared that

steady state volume had not been reached. Further studies to assess the inter-rater repeatability of residuum volume measurements using laser-based scanner systems are recommended.

4.4.2. Gait kinematics and GRFs

As shown from *Figure 4.5* to *Figure 4.15* and in *Table 4.3*, the repeatability of the gait kinematics and GRFs was excellent ($0.93 \leq \text{ICC} \leq 1.0$), with low SEM and MDD ($0.0^\circ \leq \text{SEM} \leq 1.0^\circ$) and ($0.0^\circ \leq \text{MDD} \leq 2.7^\circ$) respectively. These results were better than other intra-rater repeatability studies on healthy participants (93, 94).

4.5. Limitations and Conclusions

Study limitations

The study design had some limitations. Notably, a stronger study design would have been to conduct the gait repeatability study on one day and the residuum volume measurements on another day. Such a design would have allowed the participants in the residuum volume study to rest for a significant period of time prior to measuring the repeatability of residuum volume measurements. However, such a study design would have required two visits by each subject and hence would be more burdensome.

Conclusions

Both the laser based scanning system for measuring limb volume and gait measurement approach showed high repeatability for a single rater.

Chapter 5: Piloting the main study protocol

5.1. Introduction

This chapter summarises the piloting process that was undertaken to evaluate and potentially address any problems with the protocol design for the main study, evaluating the passive approach to maintaining residuum volume.

As the main study aims to compare the performance of the Suction Socket Suspension System (SSSS), modified SSSS, and Vacuum-Assisted Suspension System (VASS). A repeated measures study with three test-conditions was designed. Unilateral trans-tibial amputees will be recruited²⁷. Two visits to the University of Salford will be required to complete the study. The first visit will be for casting and measurements to create the test-socket and Instrument Trans-tibial Prosthesis (ITTP) for the second visit. In the second visit, the participant will be fitted with the ITTP that can be adapted to perform as a SSSS, a modified SSSS, or a VASS. Residuum volume and static pistoning will be measured before and after walking with each type (test-conditions presented in a random order). Gait and dynamic pistoning data will be collected during walking trials. Suitable time will be given between test-conditions for residuum volume to reach a steady-state (20 minutes). Finally, the comfort will be assessed after each test-condition.

To pilot the protocol for the main study, it was necessary to carry out experimental work to check the length of time taken for the setup and testing (and hence potential burden on the subjects in the main study). Also, to check for any unforeseen issues with data collection²⁸ (*Table 5.1*).

Table 5.1 shows the test-conditions through this chapter and in the following main study.

²⁷ Amputee participant should have a Self-reported problem with changes in residuum volume or pistoning, based on the study aims.

²⁸ Same test-conditions in the future main study.

Table 5.1: Test-conditions.

A	Test-socket with small distal void volume and the Limb-Logic Communicator switched OFF (SSSS with small distal void volume)
B	Test-socket with large distal void volume and the Limb-Logic Communicator switched OFF (SSSS with large distal void volume)
C	Test-socket with small distal void volume and the Limb-Logic Communicator switched ON (VASS with small distal void volume)

Therefore, the aims of this chapter were to:

1. Assess the length and acceptability of the protocol;
2. Check data collection methods worked and;
3. Identify any changes to the protocol, or data collection methods needed prior to the main study.

5.2. Methods

One participant with a unilateral trans-tibial amputation, was recruited. The following equipment was used:

- OMEGA Tracer²⁹ (Laser-based scanner system): to measure the residuum volume;
- Vicon Motion Capture System³⁰ (Optical motion capture system): to collect the pistoning and kinematics data;
- Kistler Force Plates³¹ (Force plates): to collect the GRFs data and;
- Limb-Logic Communicator³² (Vacuum pump): to create in-socket vacuum pressure when activated.

²⁹ Ohio Willow Wood, Ohio, USA

³⁰ Vicon, Oxford Metrics, Oxford, UK

³¹ Kistler, Kistler Instruments Ltd, Alton, UK

³² Ohio Willow Wood, Ohio, USA

5.2.1. Participant and recruitment

The participant was a male, aged 56 years, height 1.8 m, mass 72 kg, 14 years' post-amputation, and K4 mobility grade³³, who was recruited from the professional amputees' database employed within Salford's undergraduate Prosthetics and Orthotics (P&O) programme. There were no self-reported problems with RVFs or pistoning.

5.2.2. Experimental procedure

Two visits to the University of Salford were required to pilot the main study protocol, as explained below.

5.2.2.1. First visit

During this visit, the Principle Investigator (PI) explained and demonstrated the experimental procedure and invited the potential participant to ask any questions. If the potential participant was happy with the protocol, he was invited to sign the consent form. Following this, the PI took measurements and a cast of the participant's residuum. This process took place in the prosthetic clinic of the Brian Blatchford building, at the University of Salford. *Figure 5.1* illustrates the tasks during the first visit. The cast and measurements were used to create the test-socket and ITTP that would be needed for the second visit.

³³ (*) K-levels refer to the Medicare Functional Classification Levels (MFCLs) 89. Stout S. Do You Know Your K-Level? . *InMotion*. 2013;23(5):24-7. K4 corresponds to recreationally active.

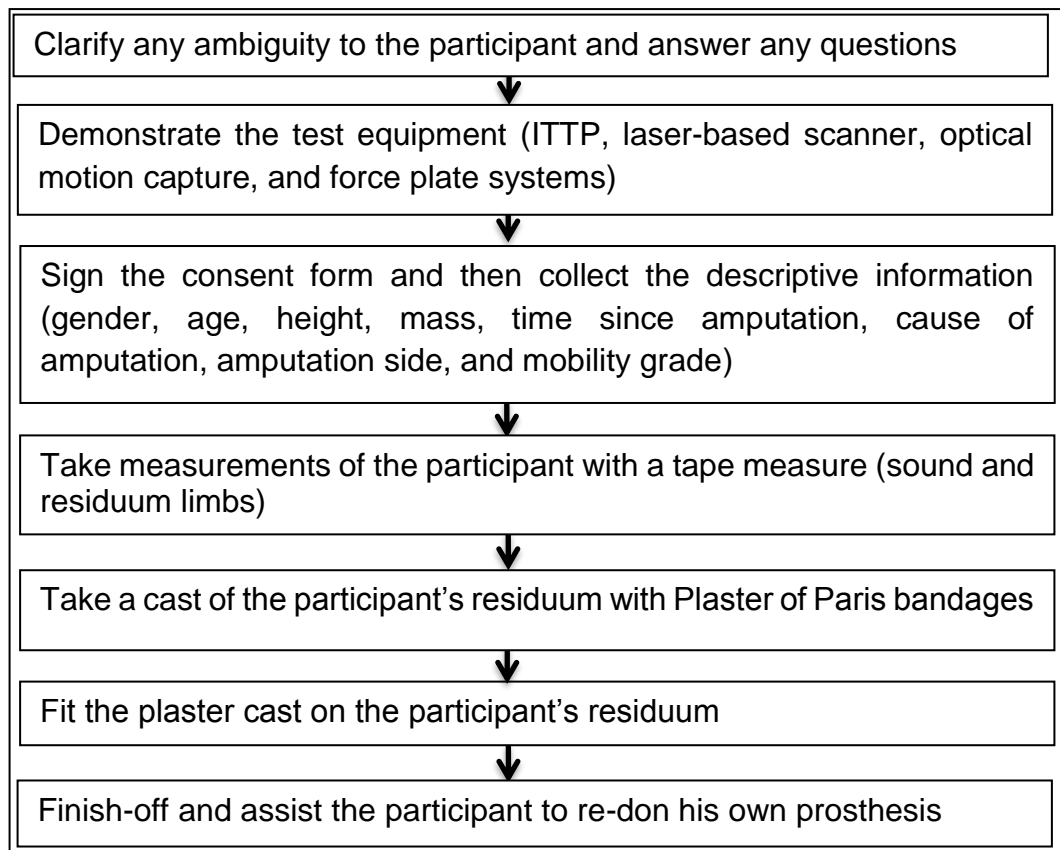


Figure 5.1: The procedures of the first visit.

5.2.2.2. Second visit

During the second visit, a series of preliminary activities were followed by data collection which took place in the gait laboratory of the Brian Blatchford building, at the University of Salford.

1. ITTP fitting

At the beginning of the second visit, the participant attended the P&O clinic of the Brian Blatchford building, at the University of Salford for: 1) socket fitting; 2) ITTP adjustment as required (prosthetic length, alignment, etc.) and; 3) practice walking between parallel bars. These processes were undertaken to ensure that the participant was confident, safe, and comfortable. Thereafter, the participant moved to the gait lab in the same building for data collection. The ITTP fitting was approximately one hour in duration.

2. Systems set-up and data collection

Four systems were used to collect the study data. The set-up and data collection for these systems were as follows:

2.1. OMEGA tracer

The OMEGA tracer system is extensively employed within clinical practice to provide 3-Dimensional (3D) images of residuums. In our study, it was used to measure the volume of each participants' residuum, with the liner already donned. It was decided that this process was more accurate than simply recording the volume of the residuum (without the liner) due to the time sensitivity for RVFs, experiment, and reaching a relatively steady-state residuum volume (77). The process of data collection using the OMEGA system is detailed in (Appendix C: Measuring the residuum volume using a laser-based scanner system). A hand-held laser scanner was connected to a laptop installed with OMEGA Tracer Software. Targets³⁴ were attached to the participants' silicone liner covering their residuum (*Figure 5.2*), to enable the scanner to capture the geometry of the residuum (plus liner). The volume of particular interest lied distal to a user-defined plane on the 3D model that was created by the OMEGA Tracer software. The plane was calculated in the software using the target placed on the distal end of the patella and a line connecting two reflective targets attached on the lateral aspect of the residuum at the proximal and distal ends. The distal end of the patella was considered as a reference point.

³⁴ Special retro-reflective markers manufactured for this laser-based scanner system; to enable the scanner from capturing the residuum anthropometry



Figure 5.2: Using laser-based scanner system to measure the residuum volume.

2.2. Vicon Motion Capture System

Ten cameras (Motion Capture Units (MCUs)) were used to capture the segments' motion and liner-socket displacement (pistoning) over a gait cycle, at a sampling frequency of 100 Hz (*Figure 5.3*). These MCUs were suitably positioned with the aim being to make each marker visible to at least two cameras over the capture volume (95). The inter-segment motion of interest related to the compensatory strategies which might be employed by amputees to compensate for positioning. These included: a) raising the pelvis on the prosthetic limb side during the swing phase (hip hiking) (56, 57); b) increasing hip and knee joint flexion of the prosthetic

limb during the swing phase (57) and/or; c) increasing the plantar-flexion of the sound limb during the stance phase (vaulting gait) (58).

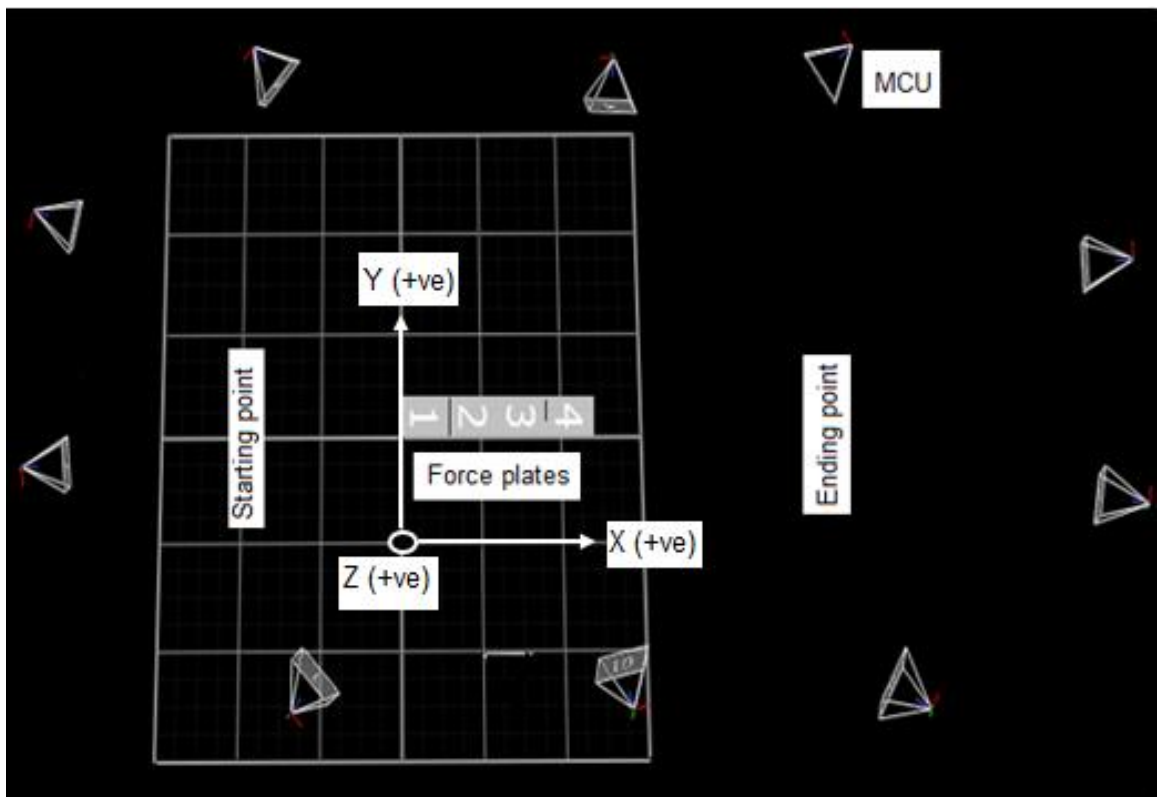


Figure 5.3: MCUs and force plates locations in the gait laboratory.

Two calibrations were required to set-up the Motion Capture System. These calibrations were:

1. Static calibration: An active wand³⁵ was placed on the first force plate where the angles of the frame and the first force plate were matched to define the origin of the Global Coordinate System (GCS) (0, 0, 0) (X, Y, Z) respectively with a right Cartesian coordinate system rule (positive X-axis pointing forward, positive Y-axis pointing to the left, and positive Z-axis pointing upward) and;

³⁵ The Vicon active wand is a T-shaped electronic motion capture calibration device that contains five pairs of LEDs.

2. Dynamic calibration: A calibration wand was moved dynamically through the MCUs' volume so that the known distances between markers on the wand could be used to calibrate the capture volume.

To capture the segments relative movements; 42 spherical retro-reflective markers were attached to the participant's pelvis and lower limbs, either singularly onto the skin, or within a cluster³⁶ (*Figure 5.4*). These markers were attached according to the Calibrated Anatomical System Technique (CAST) established by Cappozzo (87).

Static trials were captured to define the Anatomical Coordinate System (ACS). Additional reflective markers were also employed during walking trials to capture the segments' dynamic motion (Technical Coordinate System (TCS)) (87, 96). In addition, 3 paper retro-reflective markers were attached to the liner (from anterior, lateral, and posterior sides) to capture the socket-liner movements (pistoning).

Figure 5.4 illustrates the locations of the spherical retro-reflective markers on the participant.

³⁶ A rigid polyethylene plate with four retro-reflective markers mounted on it

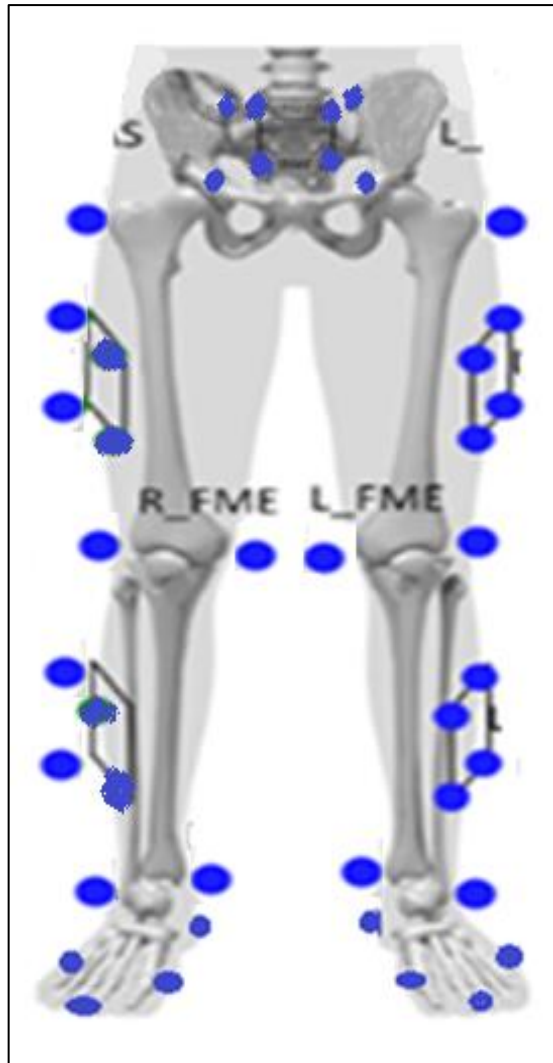


Figure 5.4: Locations of the spherical retro-reflective markers on the participant, using a CAST model.

2.3. Kistler Force Plates

Four Kistler force plates were used to capture ground reaction forces at a sampling frequency of 1000 Hz (*Figure 5.3*). Force plates were reset to zero prior collecting the GRFs data to eliminate the effect of drift.

2.4. Limb-Logic communicator

The Limb-Logic communicator (see *Figure 5.5.*) is one of the Vacuum-Assisted Suspension System (VASS), which can be used in conjunction with lower limb prostheses to create in-socket vacuum pressure, with a view to maintaining residuum volume. The Limb-Logic Communicator consists of three main components, as shown in *Figure 5.5.* The Dongle (*Figure 5.5. (A)*) is a wireless adapter that allows prosthetists to access the software of the Limb-Logic Communicator and then, set-up the vacuum pump (*Figure 5.5. (B)*). The fob (*Figure 5.5. (C)*) is a tool for prosthesis users; so they can adjust the vacuum level by pressing the up or down arrow on the fob³⁷.

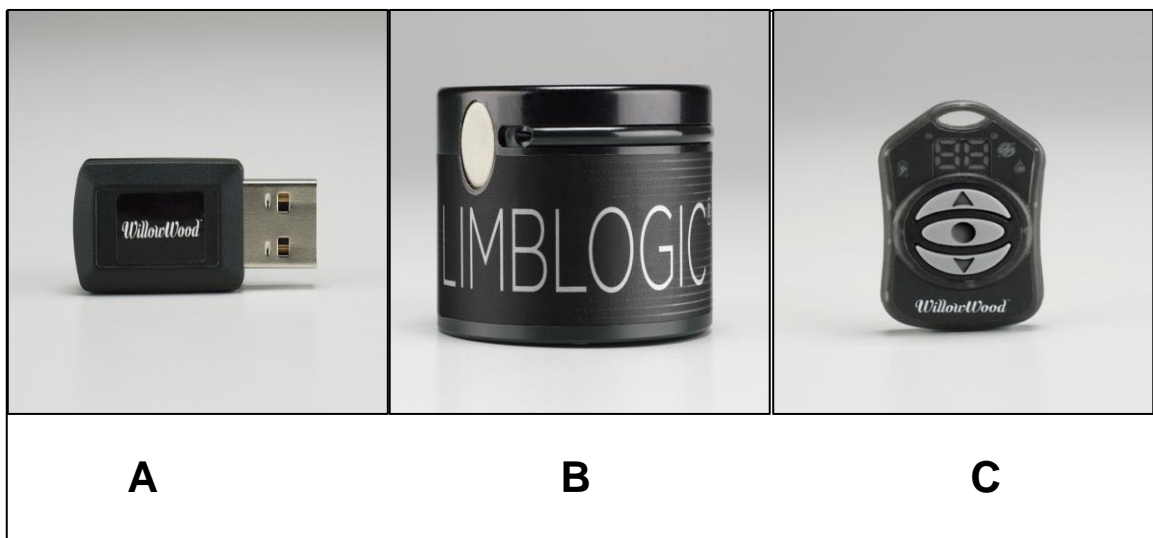


Figure 5.5: The Limb-Logic Communicator: (A) Dongle; (B) Vacuum pump; and (C) Fob.

The Limb-Logic Communicator can run under 3 different modes, as shown in *Figure 5.6:* 1) Standard mode: The vacuum pump active to create a vacuum, based on the standard mode setting (Set point and standard range). For example, if the set point is 14 inHg with a range of 4 inHg, the vacuum pump will not turn on until the vacuum drops to 10 inHg and then the pump will turn on to restore the vacuum towards the target of 14 inHg; 2) Adaptive mode: The vacuum pump will be activated to create a

³⁷ If a prosthetist does not want a patient to put the vacuum above some point; they can set the maximum below 20 inHg, for example at 16 inHg, and then the highest setting someone can adjust to using the fob would be 16 inHg.

vacuum, based on the standard mode setting (Set point and standard range) during walking, and resting setting (Resting set point and resting range) during resting and;

3) Standby mode: The vacuum pump will be deactivated and will not create any vacuum. The level of the in-socket vacuum pressure is shown through the dialogue and analogue displays, under the 3 modes of the vacuum pump. However, if the vacuum pump was unable to create an in-socket vacuum pressure due to air-leakage, the leak button will flash.

Therefore, as the main study will compare between the SSSS and VASS (see *Table 5.1*); Standby mode was selected during test-conditions A and B to deactivate the vacuum pump (passive system). For test-condition C, the VASS (active system) was required and hence, Standard mode was selected with a set point and standard range of 14 inHg and 4 inHg respectively, as shown in *Figure 5.6*. This setting was based on the advice from the manufacturer, Willow Wood Company.

Figure 5.6 shows the settings applied during test-condition C.

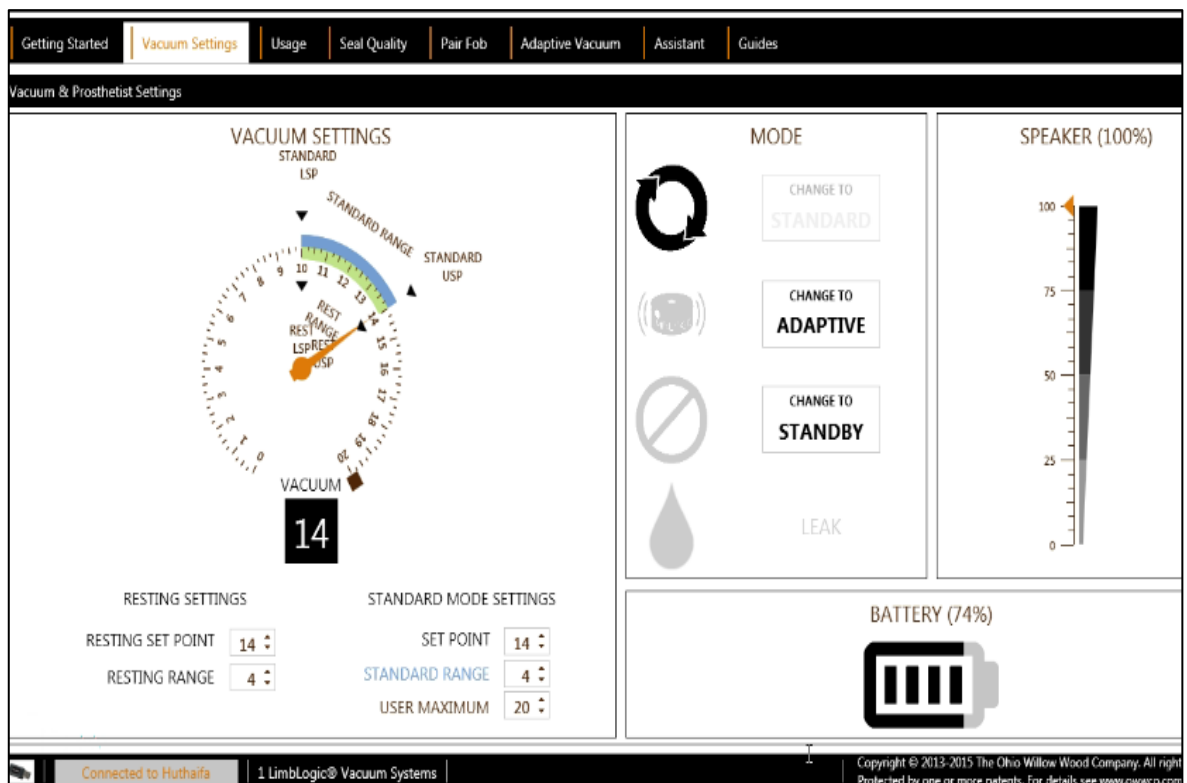


Figure 5.6: Settings for test-condition C (VASS).

Figure 5.7 Shows a participant standing with the ITTP, after successful set-up.



Figure 5.7: ITTP fitted on amputee participant after the systems set-up completed.

3. Data collection

Data was collected across the three test-conditions (*Table 5.1*) in the gait lab of the Brian Blatchford building, at the University of Salford, as explained in *Figure 5.8*.

Figure 5.8 illustrates the tasks during the second visit.

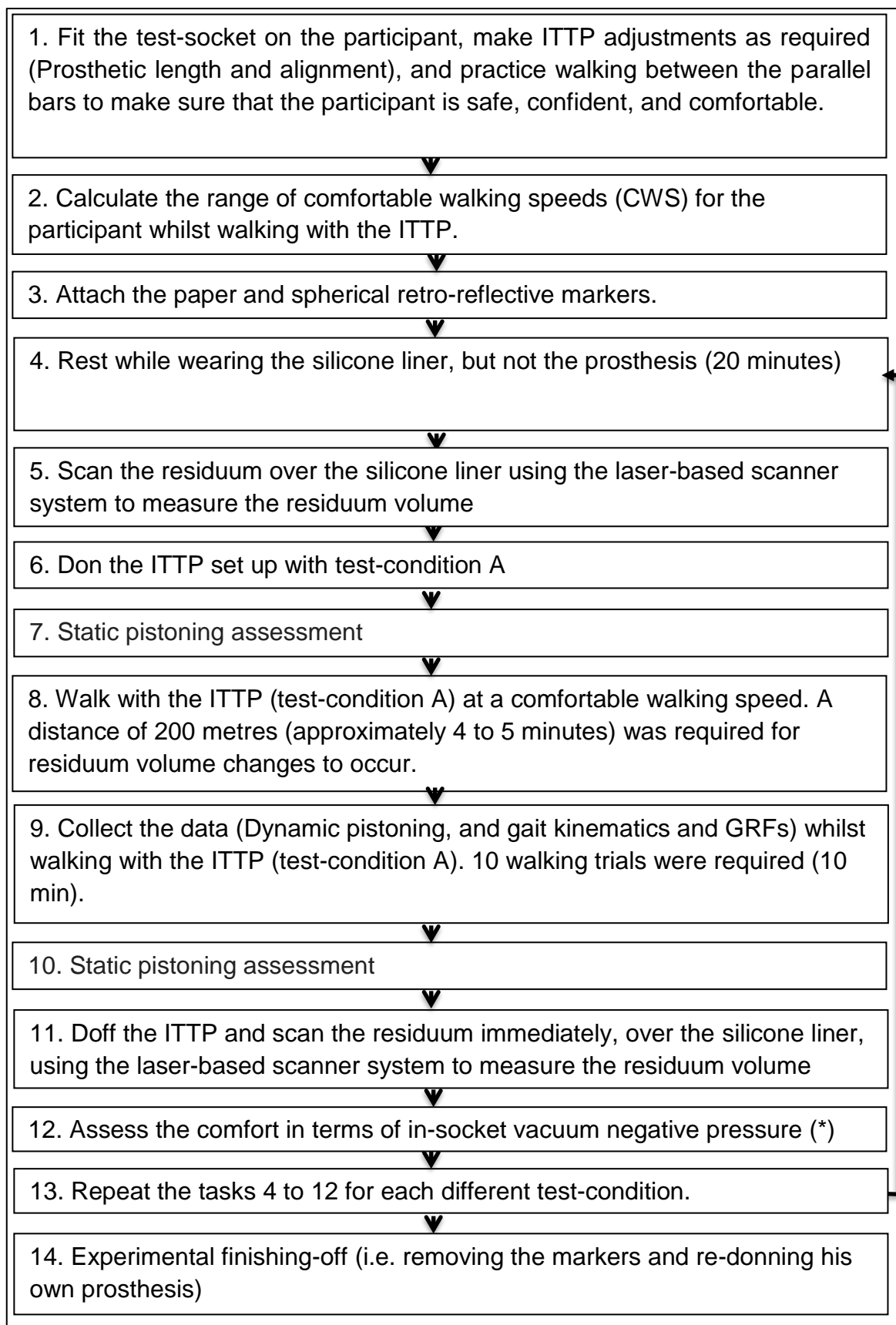


Figure 5.8: The procedures of the second visit.

(*) Comfort was assessed based on the Socket Comfort Score (SCS), which was introduced by Downie et al (97) and validated by Hanspal et al (2003) (98). This scale uses a rating between 0 (complete discomfort) and 10 (highest comfort).

5.2.3. Data analysis

The data from the force plates was transferred to the main computer in the gait lab (Vicon Nexus Software). Pistoning and gait kinematics data were processed using Vicon Nexus Software for marker labelling. These data files were then exported to Visual 3D (V3D) software³⁸ as coordinate 3D (C3D) files. The next stage was to: a) interpolate the data, filling any trajectory gaps (up to a maximum of 10 consecutive frames); b) filter the data: digitally filtering any high frequency noise with a Butterworth 4th order digital low pass filter, cut-off frequency of 6Hz for kinematics and 25Hz for GRFs data; c) detect the gait events: heel strike (foot on) and toe off (foot off) for the lower limbs and; d) report the results: residuum-liner displacement (pistoning), RoM of the frontal pelvic obliquity angle, RoM of the sagittal prosthetic hip and knee joints angles, RoM of the sagittal sound ankle joint angle, and prosthetic GRFs. These processes are explained further in Appendix D³⁹. A trial was accepted if the prosthetic foot hit one of the force plates completely and the average speed was within $\pm 5\%$ of the CWS in order to control the effects of the acceleration on the GRFs. Finally, the processed data was exported as a text file to the Microsoft Excel Software⁴⁰ to identify and present the related variables.

5.3. Results

The length of the first visit was approximately one hour in duration, while the second visit was approximately 5 hours in duration.

The Limb-Logic communicator (vacuum pump) was examined and tested⁴¹, prior to the second visit. Initially, a problem with air-leakage into the test-socket was identified, that was preventing the vacuum pump from running efficiently and

³⁸ C-motion Incorporation, Germantown, USA

³⁹ Appendix D: Using V3D Software to analyse and report gait parameters

⁴⁰ Microsoft Office Professional Plus 2010, Microsoft Corporation, Washington, USA

⁴¹ Appendix E: Testing the Limb-Logic Communicator integrated with a test-prosthesis

preventing the pump from creating the desired in-socket vacuum pressure, between 10 inHg and 14 inHg. To solve this problem, the possible locations of air-leakage were defined and addressed. These areas were the expulsion valve, socket-expulsion valve interface, socket-vacuum pump interface, and the urethane sleeve suspension. Inserting silicone between the socket and expulsion valve, covering the expulsion valve by a plastic diaphragm, and applying an extra rubber seal between the socket and vacuum pump were needed to re-establish the correct vacuum ranges. Assessing the air-leakage into the urethane sleeve suspension was difficult without a residuum; therefore, the sleeve suspension could only be assessed during the static alignment and fitting process of the ITTP.

The results of residuum volume, gait kinematics and GRFs were acceptable. By contrast, the results of pistoning were not useful, as shown below.

Figure 5.9 shows pistoning data from one walking trial.

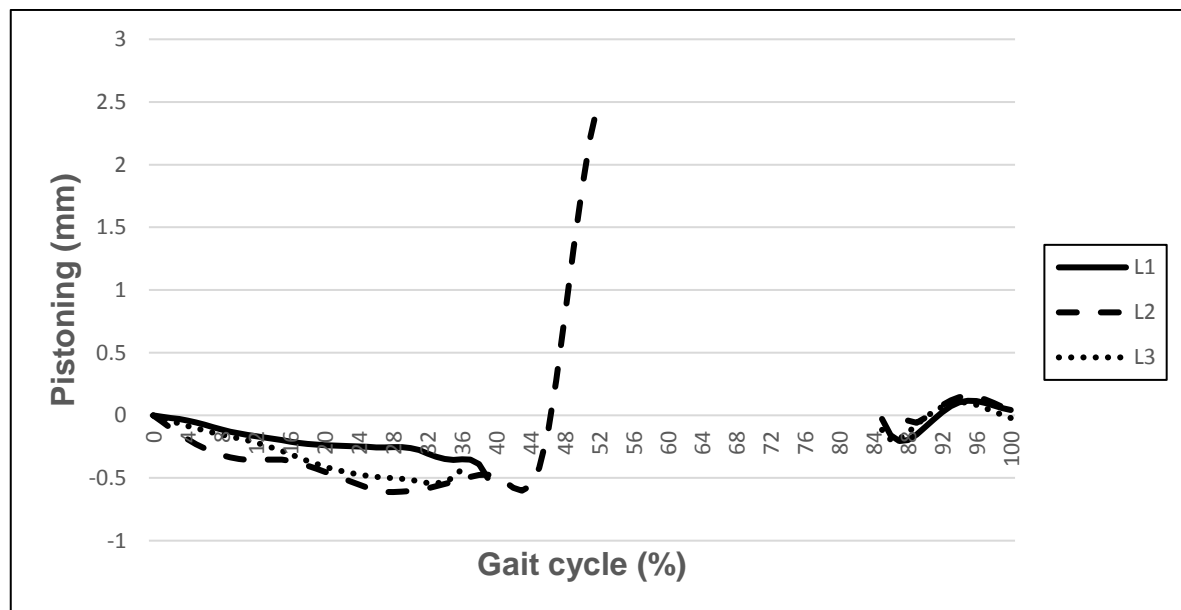


Figure 5.9: An example of pistoning measured during one walking trial in test-condition A.

5.4. Discussion

The duration of the first visit was an hour. The second visit was approximately 5 hours, longer than had been hoped for or anticipated. It was decided to reduce the protocol time by eliminating the static pistoning assessment.

Comfort scores were determined by the participant without difficulty. Data related to gait kinematics and GRF variables were also collected and analysed without any problems.

Pistoning data were poor (*Figure 5.9*) due to the following issues: 1) The reflections from the paper markers were not easily captured by the MCUs as the marker profile was flatter than was the case in spherical markers, leading to reduced spread in reflected light back to the cameras; 2) the urethane sleeve suspension was folded over the top of the socket and hence covered approximately half of the area. This made the available area for attaching the paper markers to the liner relatively small, creating difficulties in tracking markers; 3) the MCUs in the Brian Blatchford lab are in fixed positions which were less than ideal for capturing the markers on the liner; 4) the visibility of the paper markers through the transparent thermoplastic material was limited. As a result, none of the paper markers was captured by the MCUs over an entire gait cycle. Typically, the paper markers disappeared for more than 40 frames out of 100 frames per gait cycle and; 5) confusion between reflections from the targets of the scanner and the paper markers made differentiating between them challenging.

The pistoning results suggested that capturing good quality data, using the materials and techniques at our disposal would be very difficult. Nevertheless, as the placement of paper markers added negligible time to the protocol, it was decided to keep these markers during the walking trials and review the pistoning data during walking, once the main data were collected.

Based on the previous discussion, the required amendments were applied to the study protocol and the revised protocol is shown in *Figure 5.10*.

Figure 5.10 shows the amended procedures of the second visit.

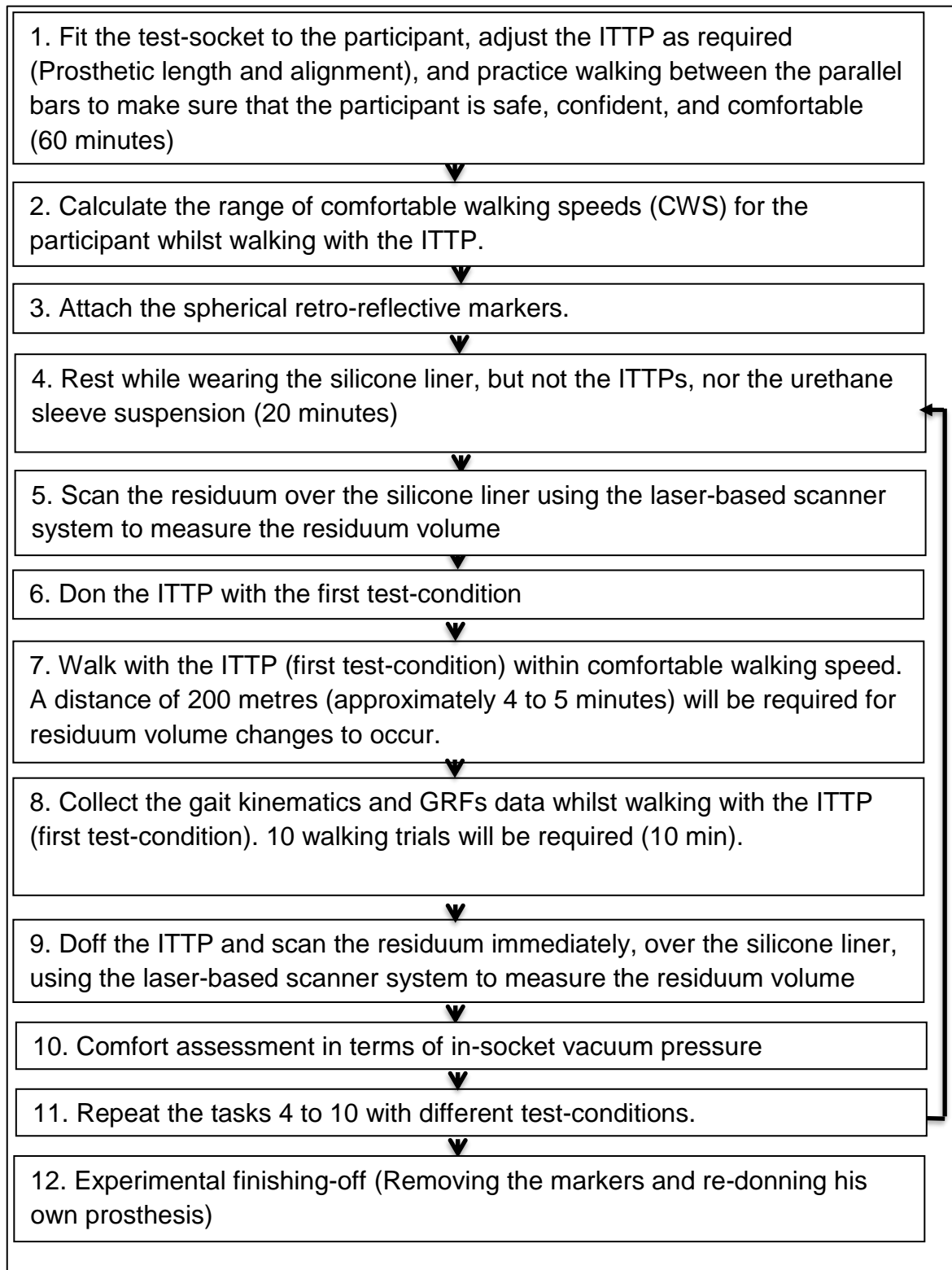


Figure 5.10: The amended procedures of the second visit.

5.5. Conclusions

The PI was able to fabricate a test-socket and assemble the ITTP based on the requirements of the main study, collect and analyse related data, and amendments to the study protocol were identified and applied.

Chapter 6: Investigation of the effects of a novel passive socket system on short-term changes in residuum volume, comfort, and gait kinematics and ground reaction forces: A preliminary study in trans-tibial amputees

6.1. Introduction

Changes in residuum volume are often reported by amputees, due in part to their compromised circulatory system. The consequences of these volume changes can be significant. If the residuum volume reduces, the socket fit becomes looser and pistoning (displacement of the socket relative to the residuum) can result. Pistoning can lead to gait asymmetry (21), residuum pain (46), as well as longer term damage to the residuum tissue (51).

One factor which may impact on how the residuum volume changes with time is the in-socket air pressure. Three small scale studies (1-3) have demonstrated that using an active system (Vacuum-Assisted Suspension System (VASS)) to maintain a below-atmosphere in-socket air pressure while walking can help to reduce the reduction in residuum volume. However, such devices are expensive and require specialist fitting. This study explores whether similar outcomes can be achieved using a modified passive system (modified Suction Socket Suspension System (modified SSSS))⁴².

The aims of this study were to:

1. Build a test prosthesis that allow participants to be tested while walking with a SSSS, a modified SSSS, and a VASS.

⁴² The passive socket design described in (Chapter 3: Instrumented Trans-tibial Prosthesis (ITTP)).

2. Use the new prosthesis to compare the performance of the SSSS, modified SSSS, and VASS in terms of:
 - Maintenance of residuum volume;
 - Comfort and;
 - Gait kinematics and Ground Reaction Forces (GRFs).

6.2. Methods

The methods are explained in the following sections.

6.2.1. Participants and recruitment

Following ethical approvals from the University of Salford (UoS) (Appendix F.1) and the National Health Service (NHS) (Appendix F.2), five amputee participants took part in this study (3 males and 2 females), aged 49.2 ± 16.6 years, height 1.73 ± 0.07 m, mass 85.8 ± 8.2 kg, 25.8 ± 12.6 years since amputation, and K2/K3 of mobility grade (*Table 6.1*). The participants were recruited from the professional amputees database employed within Salford's undergraduate Prosthetics and Orthotics (P&O) programme and through the NHS. A poster to encourage further participants (Appendix F.5) was displayed at the local PACE rehabilitation centre⁴³ and posted onto UK amputees groups in Facebook, but did not result in any further recruitment.

Inclusion criteria:

- Unilateral trans-tibial amputation level;
- Self-reported problem with changes in residuum volume or pistoning;
- Distance between the distal end of residuum and ground to be at least 27 cm (to allow for assembly of the test-prosthesis);
- Distance from patellar tendon to the distal end of the residuum to be at least 10 cm;
- Over 18 years old;

⁴³ A private rehabilitation centre for amputees at Cheadle, Stockport.

- Able to walk continuously and comfortably for at least 200 metres during each test-condition;
- Able to visit the University of Salford twice and;
- Able to understand both written and spoken English.

Exclusion criteria:

- Self-reported history of falls or dizziness while standing or walking
- Unhealthy residuum (evidence of cuts, or open wounds) and/or;
- History of renal failure.

However, additional safety precautions were taken if a participant was recruited who had upper limb, or bilateral lower limb absence. Two people were available for each of the walking trials, should an extra person be needed to ensure the safety of the participant (for example, by offering to steady them during the walking trials if required). If the participant was uncomfortable with this safety procedure, a gait belt could be used as an alternative. This approach would minimise the risk of injury if a trip or fall occurs and is common practice when testing particularly vulnerable populations. While walking with the participant will affect the quality of the gait data (a secondary outcome), the primary outcome data (RVFs) would be unaffected.

Table 6.1: Participants' characteristics.

Participant	Gender	Age (Years)	Height (m)	Mass (Kg)	Time since amputation (Years)	Cause of amputation	Amputation side	Mobility grade ⁴⁴
1	Male	67	1.79	101	32	Trauma	Left	K3
2	Female	37	1.64	85	4	Vascular	Left	K2
3	Female	27	1.67	57	27	Congenital	Left	K3
4	Male	58	1.80	102	30	Trauma	Left	K2
5	Male	57	1.74	84	36	Trauma	Right	K2
Mean \pm SD		49.2 \pm 16.6	1.73 \pm 0.07	85.8 \pm 18.2	25.8 \pm 12.6			

Figure 6.1 summarises the participant recruitment and involvement process. Each participant was given at least 24 hours to read the participant information sheet before consenting.

⁴⁴ K-levels refer to the Medicare Functional Classification Levels (MFCLs) 89. Stout S. Do You Know Your K-Level? . *InMotion*. 2013;23(5):24-7.. K2 corresponds to using walking aids outdoor; K3 level corresponds to community ambulation.

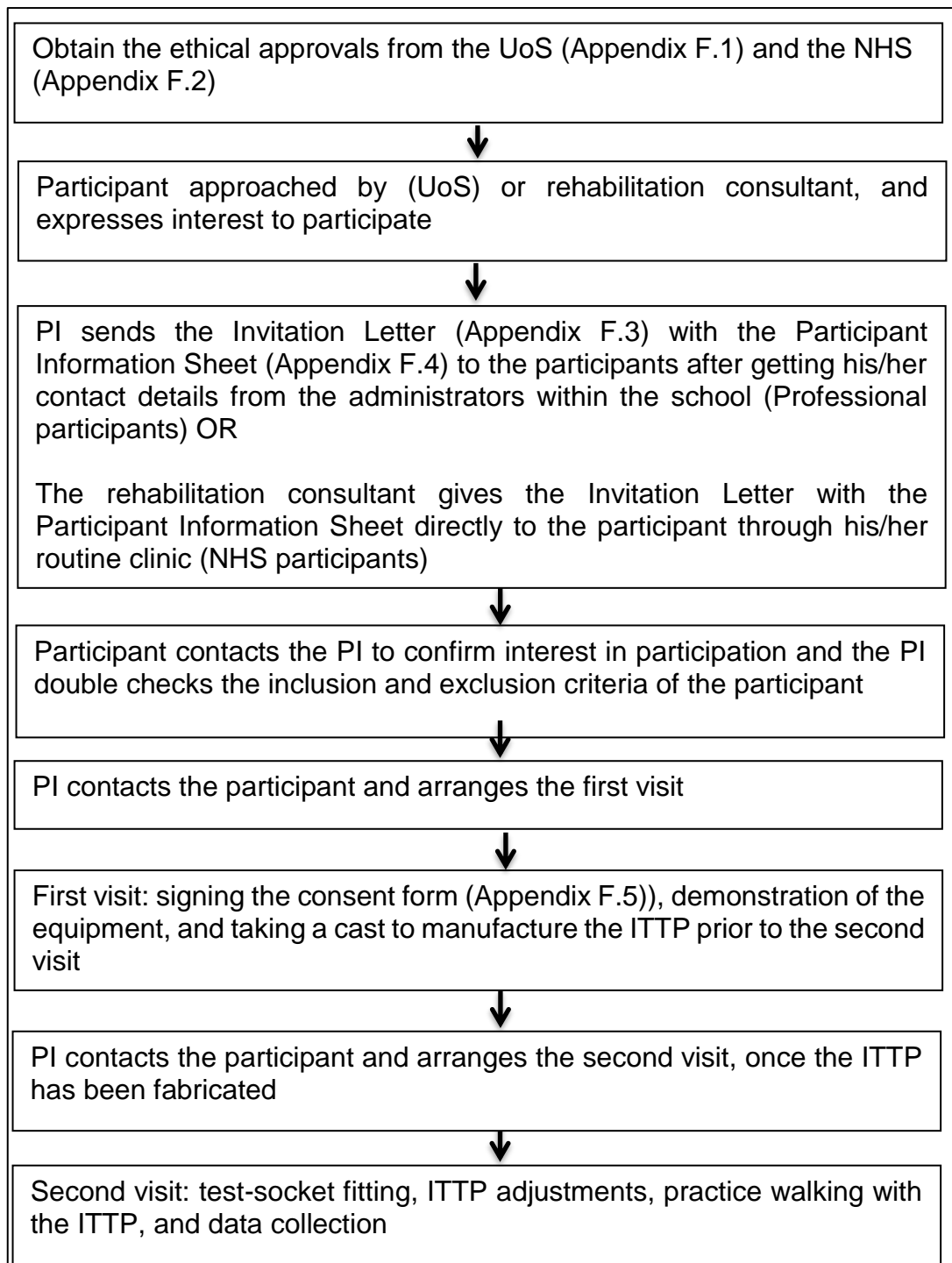


Figure 6.1: Participant recruitment and involvement process.

6.2.2. Experimental procedure

Two visits to the University of Salford were required for each participant to complete the study (*Figure 6.2*). The order of testing was randomised for the participants across the test-conditions⁴⁵; to account for possible order-related effects⁴⁶.

Table 6.2 shows the test-conditions through this study.

Table 6.2: Test-conditions.

A	Test-socket with small distal void volume and the Limb-Logic Communicator switched OFF (SSSS with small distal void volume)
B	Test-socket with large distal void volume and the Limb-Logic Communicator switched OFF (SSSS with large distal void volume)
C	Test-socket with small distal void volume and the Limb-Logic Communicator switched ON (VASS with small distal void volume)

The following equipment was used:

1. OMEGA Tracer⁴⁷ (Laser-based scanner system): to measure the residuum volume;
2. Vicon Motion Capture System⁴⁸ (Optical motion capture system): to collect the kinematics data during gait;
3. Kistler Force Plates⁴⁹ (Force plates): to collect the GRFs data and;
4. Limb-Logic Communicator⁵⁰ (Vacuum pump): to create in-socket vacuum pressure when activated.

⁴⁵ Appendix G: Randomisation plane for the main study (Chapter 6)

⁴⁶ www.randomization.com web was used to define the sequence of the test-conditions that each participant has to follow during the data collection.

⁴⁷ Ohio Willow Wood, Ohio, USA

⁴⁸ Vicon, Oxford Metrics, Oxford, UK

⁴⁹ Kistler, Kistler Instruments Ltd, Alton, UK

⁵⁰ Ohio Willow Wood, Ohio, USA

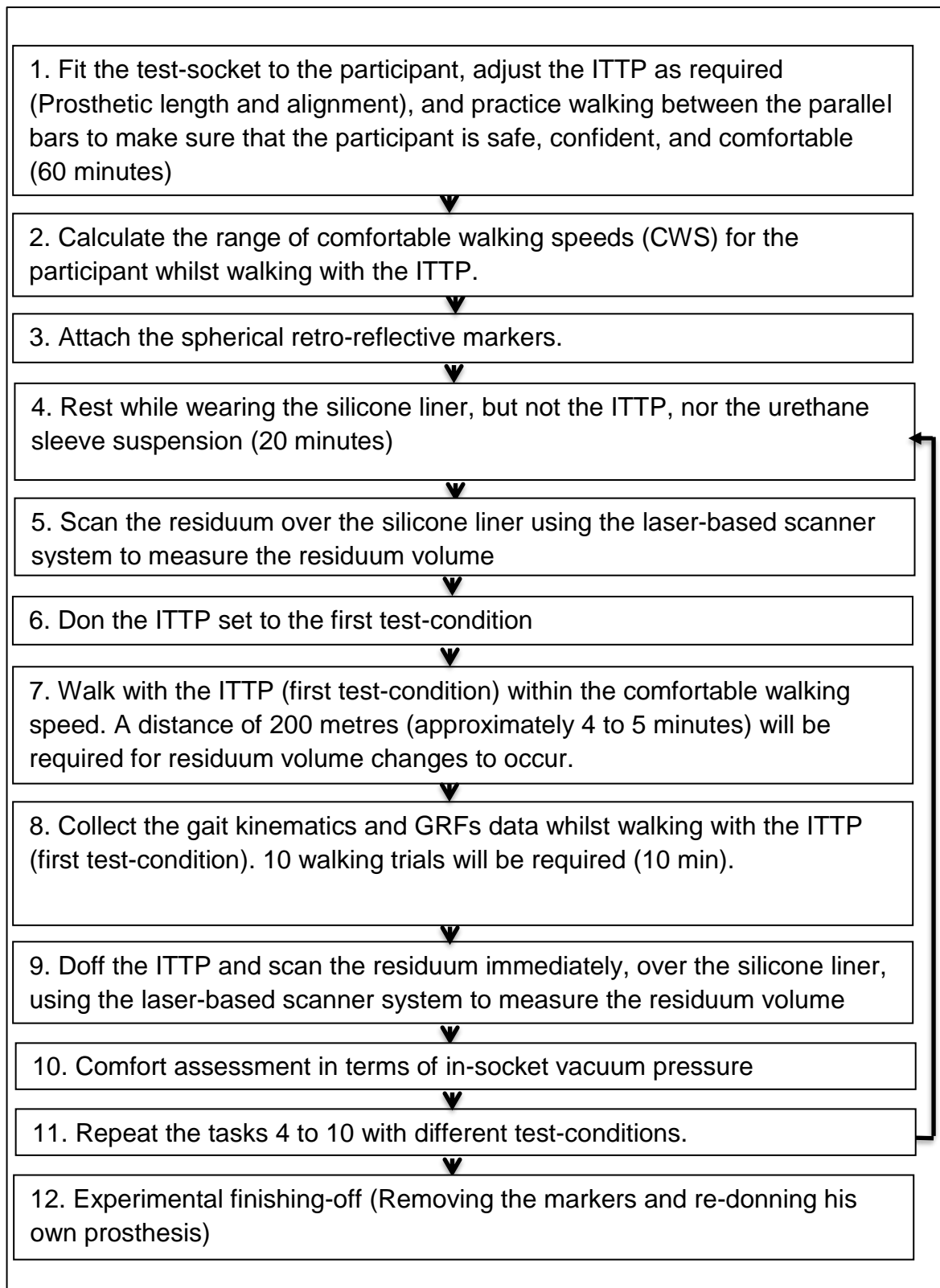


Figure 6.2: The procedures of the second visit.

6.2.3. Data analysis

OMEGA Tracer software was used to calculate the residuum volume prior to and after the walking trials, across the 3 test-conditions. The distal end of the patella was considered as a reference point for residuum volume calculations. Finally, the change in RV were calculated using formula (1).

$$\text{Change in residuum volume} = \frac{V_{\text{doff}} - V_{\text{baseline}}}{V_{\text{baseline}}} * 100\% \quad (1)$$

Where, V_{baseline} and V_{doff} are the residuum volume before and after walking with the ITTP.

Participants' comfort and gait kinematics and GRF data were scored/processed as explained in (Chapter 5: Piloting the main study protocol).

6.2.4. Statistical analysis

The residuum volume results and comfort results were tested using the Statistical Package for Social Sciences (SPSS) software⁵¹ (99). The normality of distribution of the RVFs and comfort were firstly checked using the Shapiro-Wilk test⁵². If the exported data was normally distributed (P-value > 0.05), a one-way repeated measures ANOVA was applied (see *Figure 6.3*). If the data was not normally distributed (P-value ≤ 0.05), a Friedman test⁵³ was applied (99). Regarding the Friedman test, if $P > 0.05$, then there are no significant differences between the test-conditions. In contrast, if $P \leq 0.05$, then there are significant differences for the related outcome between the test-conditions; therefore, Wilcoxon signed rank tests (including post-hoc tests) would be used to identify where the pairwise differences occurred between the test-conditions (99). A Bonferroni adjustment for multiple comparisons was selected to adjust the P value (99) ($P\text{-value} = 0.05/3 \approx 0.0167$) was applied to the multiple Wilcoxon tests to identify which pairwise comparisons differ (99). Thus, if $P > 0.0167$, then there are no significant differences, while if the

⁵¹ IBM SPSS Statistics 20, SPSS Incorporation, Chicago, USA

⁵² This test was selected whereby the sample size was less than 50 participants.

⁵³ A nonparametric alternative for a repeated-measures ANOVA.

$P \leq 0.0167$, then there are significant differences for the related outcomes between the test-conditions (see *Figure 6.3*).

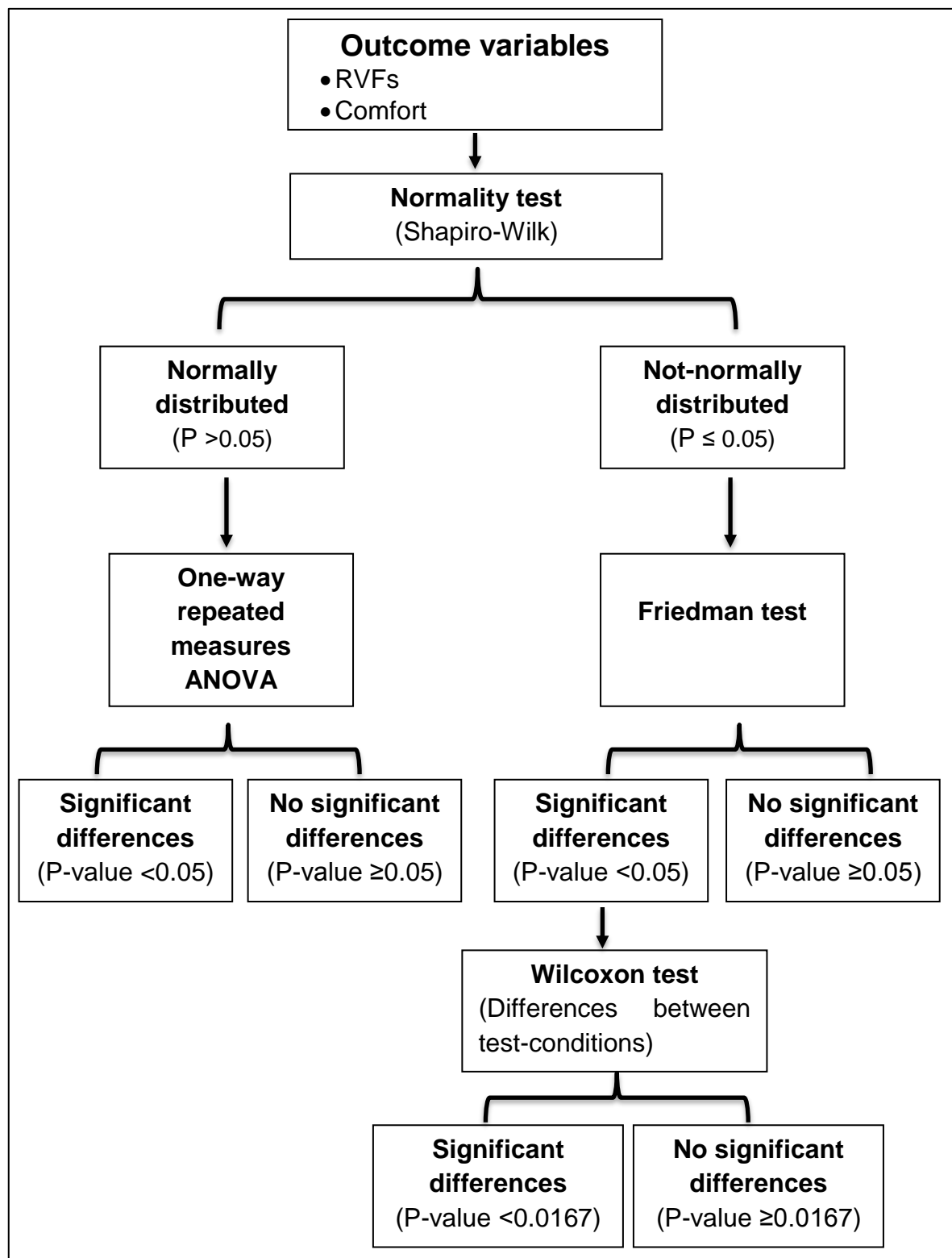


Figure 6.3: Outline of the statistical analysis in this chapter.

6.3. Results

The results are illustrated in the following sections.

6.3.1. Residuum volume fluctuations

Figure 6.4 and Figure 6.5 show the residuum volume change across the three test-conditions.

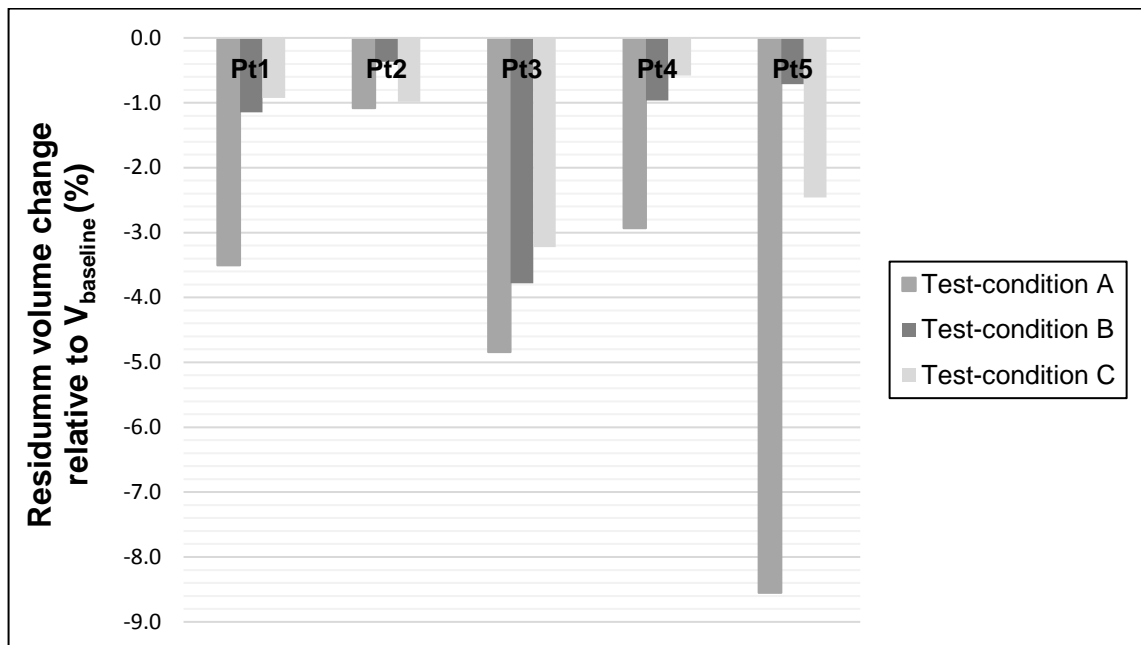


Figure 6.4: Residuum volume change relative to baseline (%) across the three test-conditions, for each participant.

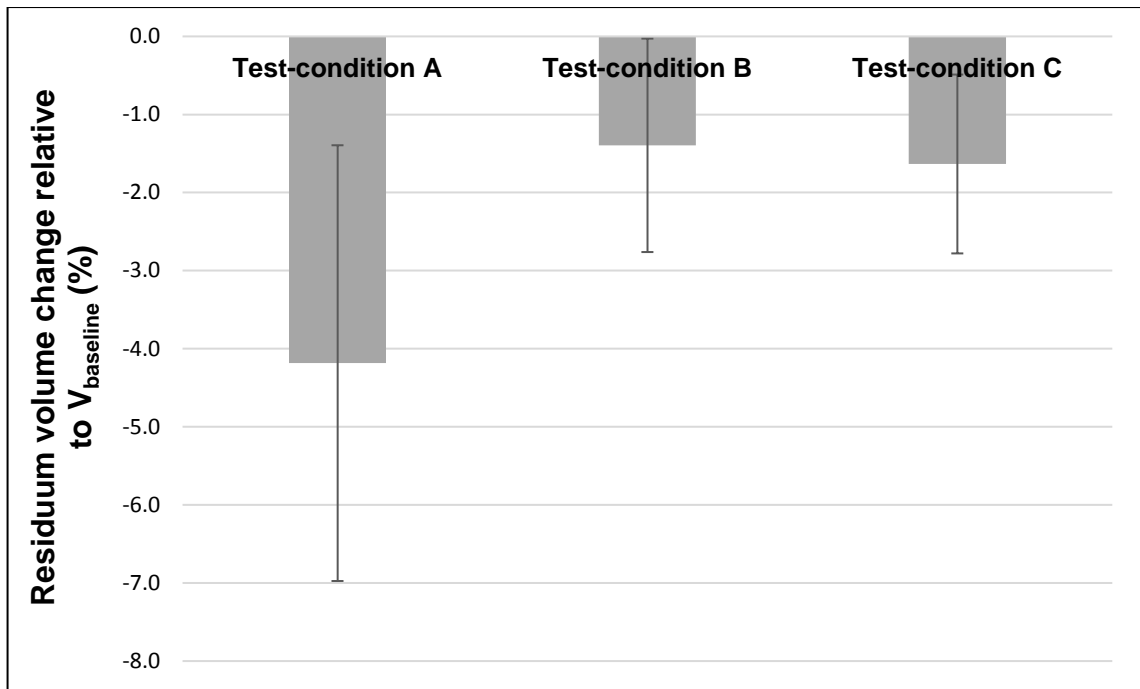


Figure 6.5: Mean residuum volume change relative to $V_{baseline}$ (%) across the three test-conditions (Mean \pm SD), for all participants.

As shown in *Figure 6.5*, the residuum volume decreased by an average \pm Standard deviation (SD) of $4.2\% \pm 2.8\%$, $1.4\% \pm 1.4\%$, and $1.6\% \pm 1.1\%$, relative to baseline volume ($V_{baseline}$), during test-conditions A, B, and C respectively. A Shapiro-Wilk test indicated that the RVFs data for test-condition B were not normally distributed ($W_{(5)} \geq 0.756$, $P \geq 0.034$) (Appendix H, *Table H.1*). Thus, a Friedman test was applied. The Friedman test ($X^2 = 7.6$, $P = 0.024$) indicated that the RVFs mean ranks differed across the test-conditions ($P \leq 0.05$) (Appendix H, *Table H.2*). Post-hoc Wilcoxon matched pairs were then applied, with a Bonferroni adjustment ($Z \geq -2.023$, $P \geq 0.063$), and these indicated that the RVFs mean ranks did not differ across the test-conditions ($P > 0.0167$) (Appendix H, *Table H.3*).

6.3.2. Comfort

Figure 6.6 and Figure 6.7 show the comfort scores across the three test-conditions.

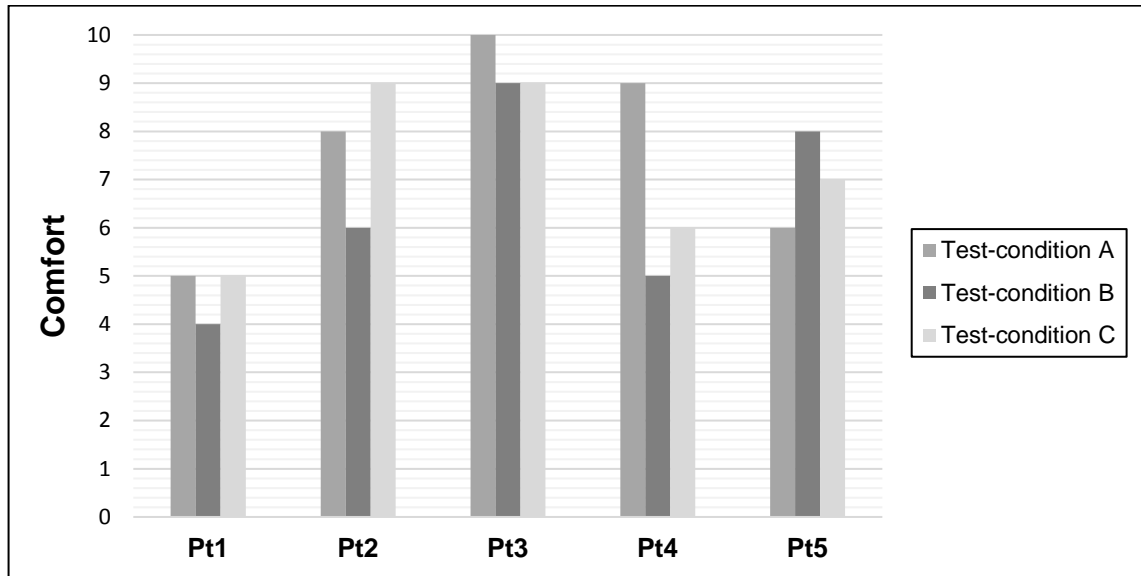


Figure 6.6: Self-reported comfort (0 to 10 (maximum comfort)) across the three test-conditions, for each participant.

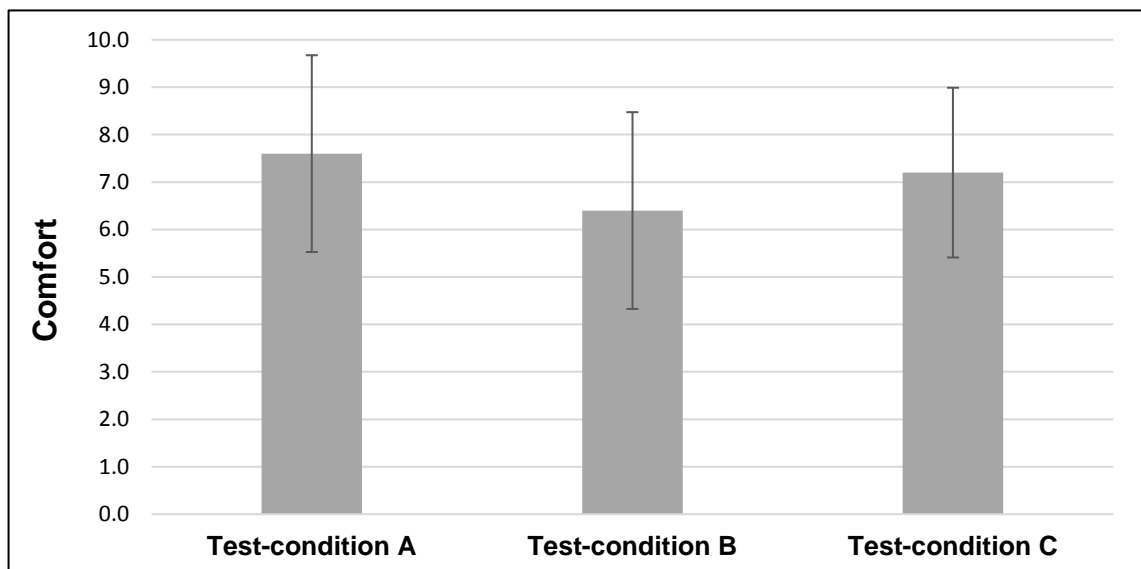


Figure 6.7: Mean comfort scores (0 to 10 (maximum comfort)) across the three test-conditions (Mean \pm SD), for all participants.

As shown in *Figure 6.7*, the comfort (out of 10) average \pm SD was 7.6 ± 2.1 , 6.4 ± 2.1 , and 7.2 ± 1.8 during test-conditions A, B, and C respectively. A Shapiro-Wilk test indicated that the comfort data was normally distributed ($W_{(5)} \geq 0.894$, $P \geq 0.377$) (Appendix H, *Table H.4*). Consequently, a one-way repeated measures ANOVA test was applied. The one-way repeated measures ANOVA ($F = 1.155$, $P > 0.363$) indicated that the comfort mean ranks did not differ significantly across the three test-conditions (Appendix H, *Table H.5*).

6.3.3. Gait kinematics and GRFs

Figure 6.8 and *Figure 6.11* show the kinematics (compensatory mechanisms) for 4 out of 5 participants. However, the additional safety precautions were taken with the fifth participant who had a right trans-humeral amputation in addition to the trans-tibial amputation. Thus, gait data were not available on participant Pt5.

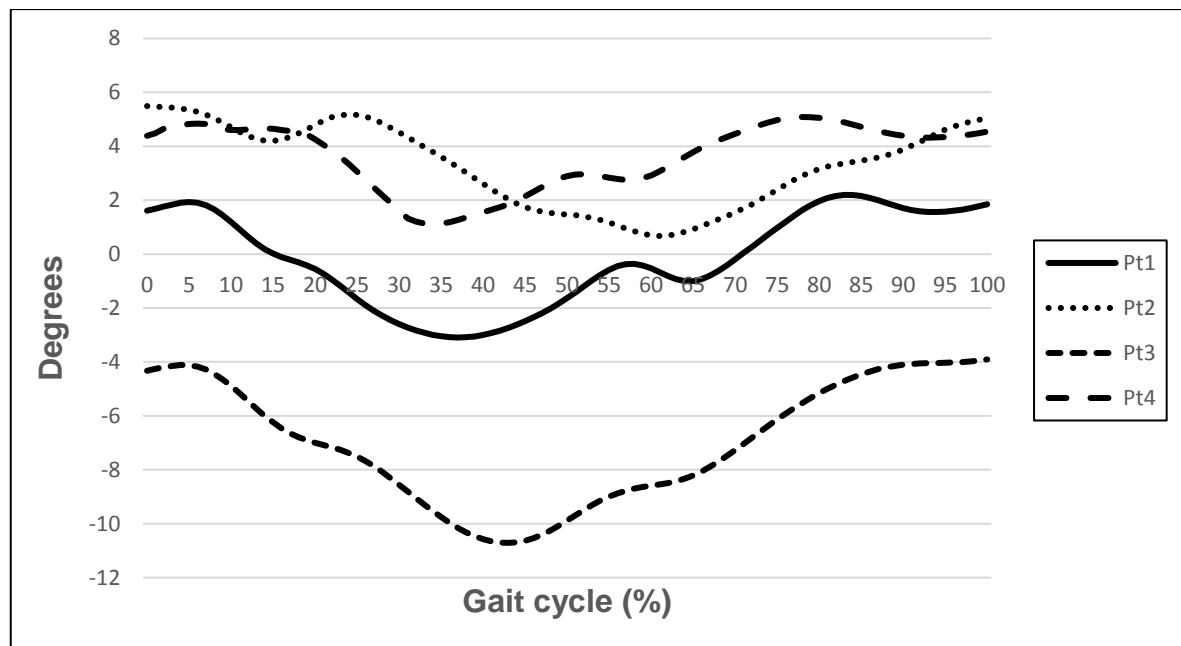


Figure 6.8: Frontal pelvic obliquity on the prosthetic limb side for 4 out of 5 participants during test-condition A.

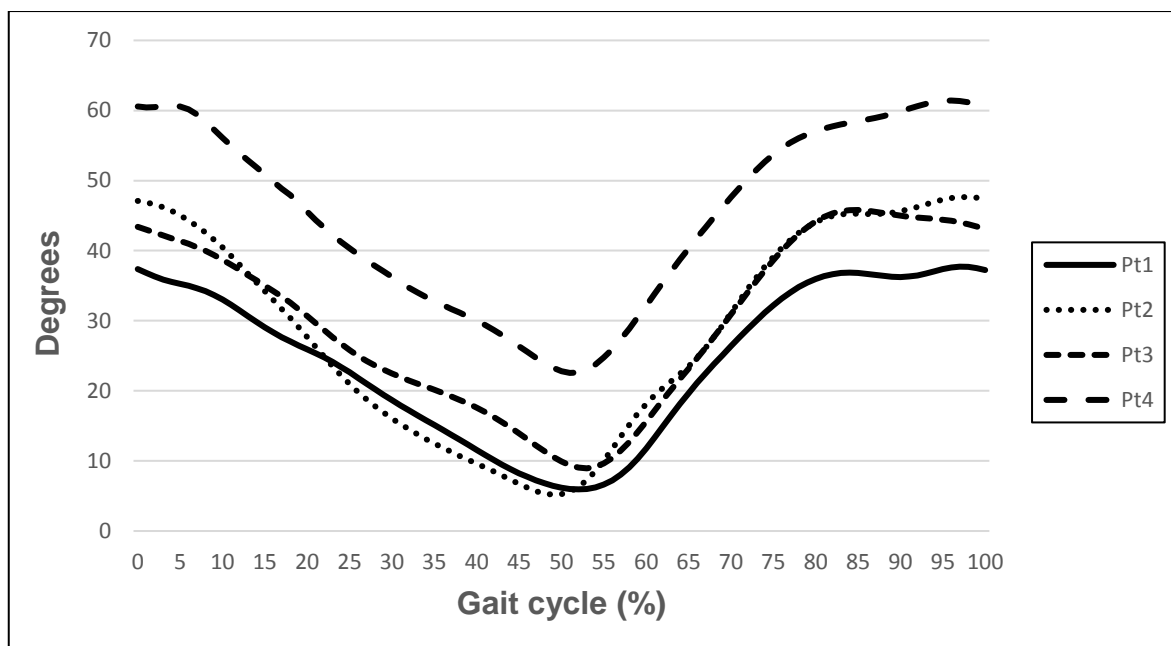


Figure 6.9: Sagittal hip joint prosthetic angle for 4 out of 5 participants during test-condition A.

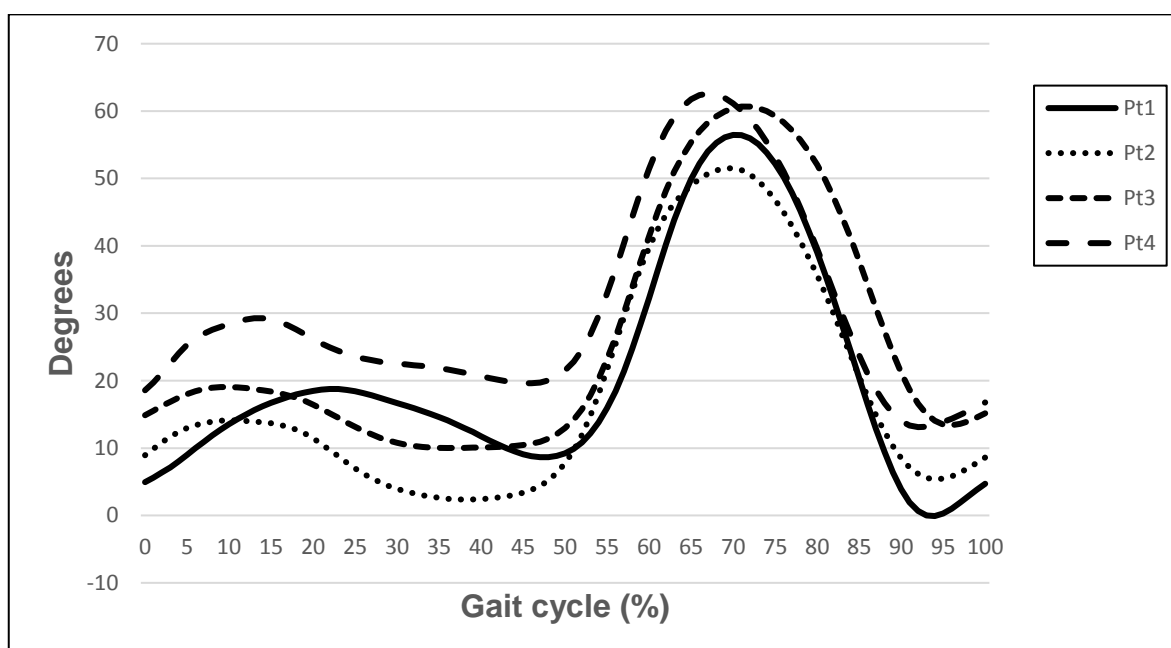


Figure 6.10: Sagittal knee joint prosthetic angle for 4 out of 5 participants during test-condition A.

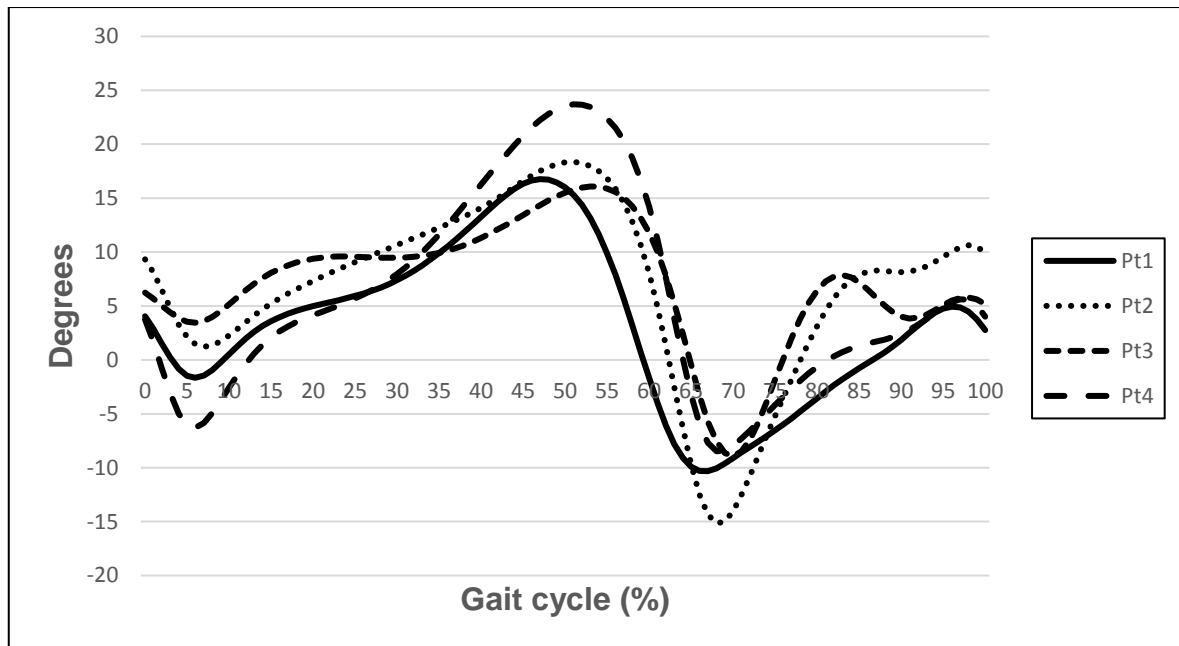


Figure 6.11: Sagittal ankle joint angle for 4 out of 5 participants during test-condition A.

6.4. Discussion

6.4.1. Residuum volume fluctuations

The RVFs results, for Pt1, Pt3, and Pt4 were consistent with the assumption in (Chapter 3: ITTP); using SSSS with a large distal void volume (Modified SSSS (test-condition B)) may decrease the in-socket air pressure and this in turn, may reduce the reduction in residuum volume during walking, when compared to a SSSS with a small distal void volume (test-condition A). During test-condition C, the vacuum pump was activated (VASS), creating a below atmospheric in-socket air pressure during walking. For Pt2, the differences between measurements were small, less than 1%. For Pt5, RVFs may have been affected by the sequence of test-conditions due to sweating. However, the test-sequences generally had little obvious effect on the residuum volume change relative to V_{baseline} (see *Figure 6.12*).

Comparing these with published data from other studies (1-3) gives some confidence in the findings, as shown in *Figure 6.13*.

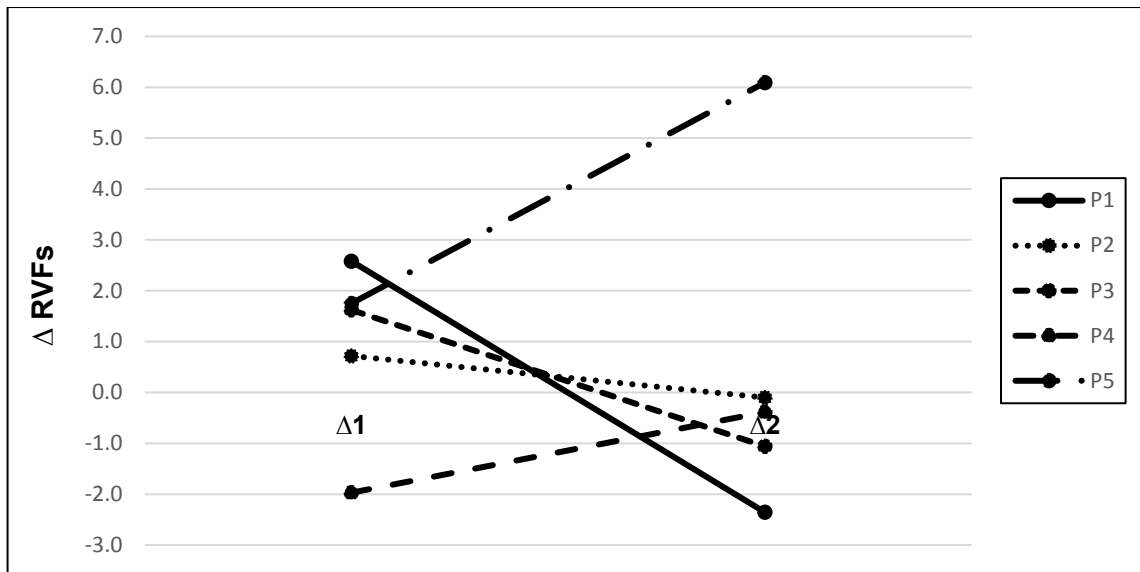


Figure 6.12: Changes of RVFs for all participants. $\Delta 1$ is the difference of RVFs between the first and second test-conditions, while $\Delta 2$ is the difference of RVFs between the second and third test-conditions. Test sequences were already randomised for all participants across the 3 test-conditions (Appendix F).



Figure 6.13: A comparison of residuum volume change relative to $V_{baseline}$ (%) from this study and associated literature (1-3), calculated using formula (1). Positive and negative signs indicate increase and decrease in residuum volume respectively. Note – different protocols were used in each study.

Board et al (2001) (2) showed that residuum volume decreased by an average (range) of 6.5% (-11.3% to -1.7%) and increased by 3.7% (-1.6% to 8.5%), relative to V_{baseline} , with SSSS and VASS respectively. Board et al (2001) noted that the participants may have used their prostheses for up to 2 hours prior to the session and may not have given sufficient time for the volume to return to a steady V_{baseline} . Further, they reported using slightly large-fitting test-socket, which may also have affected the changes seen in residuum volume. Finally, there were differences between the amputee participants in both studies, including the cause of amputation, which may have influenced the results.

Sanders et al (2011) (3) reported that the residuum volume decreased by an average (range) of 0.1% (-0.5% to 0.3%) and increased by 0.3% (-0.6% to 1.2%) while using the SSSS and VASS respectively (3). The bio-impedance technique used makes direct comparison with the results difficult. However, a few points are worth noting. In our study an electronic vacuum pump was applied, unlike the mechanical one used in Sanders et al (2011) (3). The electronic pump can create the vacuum pressure during walking, while the mechanical pump would release pressure above atmospheric pressure during the stance phase only. In addition, data were collected over approximately 3 hours in this study, while in Sanders et al (2011) the time period for collection was less than 40 minutes. Finally, participants in this study were not fitted with the VASS system before the second visit. By contrast, Sanders et al (2011) fitted the participants with the VASS system 3 to 4 weeks prior to data collection.

Gerschutz et al (2010) (1) reported that residuum volume decreased by an average (range) of 2.4% (-1.6% to -2.9%) and 0.4% (-0.3% to -0.5%), relative to V_{baseline} , for SSSS and VASS respectively.

In conclusion, although not statistically significant, the trend towards the performance of the SSSS, in terms of reducing the reduction in residuum volume, may be improved by selecting a suitably large initial distal void volume (additional ~100 ml). The results of the RVFs from Pt5 suggest that further studies on the effect of sweating on residuum volume changes are required.

6.4.2. Comfort

All the participants, except Pt5 ⁵⁴, demonstrated the lowest comfort scores for test-condition B (modified SSSS). The possible explanation for this the participant potentially taking more load on the sensitive distal end of the residuum.

In conclusion, the large distal void volume should be re-designed with a smaller diameter cylindrical extension and good cushioning at the bottom of the socket.

6.4.3. Gait kinematics and GRFs

The results of gait kinematics (compensatory strategies) and GRFs showed variations both between participants (*Figure 6.8 to Figure 6.11*) and within participants (Appendix I). However, it was difficult to compare and test the gait results between and within participants due to: 1) participants adapting their gait using different compensatory mechanisms; 2) participants showing differing levels of confidence whilst wearing the ITTP and 3) walking preferences; Pt2 and Pt4 used a cane during the walking trials, Pt3 has a prosthetic knee flexion contracture ($\sim 35^\circ$), and Pt5 has a right trans-humeral amputation and/or more importantly; 4) the amount of pistoning was not measurable, making the differences in the compensatory mechanisms to pistoning impossible to judge.

6.5. Conclusions

The performance of SSSS in maintaining the residuum volume can be improved by fabricating the prosthetic socket with a large distal void volume (additional ~ 100); however, further studies on the effect of sweating on residuum volume changes are required. Also, this study did not manage to collect the in-socket air pressure data, due to problems with the limb-logic Communicator⁵⁵, future studies are needed to obtain the pressure profile data.

⁵⁴ Comfort was reduced over time for Pt5 due to sweating; this led to reduction in residuum volume (pistoning).

⁵⁵ Appendix J: The investigation into obtaining in-socket air pressure profile from the Limb-Logic Communicator

Chapter 7: Discussion and conclusions

7.1. Introduction

Lower limb amputees commonly report a reduction in residuum volume, associated pistoning and hence, gait asymmetry (21), residuum pain (46), and in the longer term, damage to tissue (3, 50, 51), and addressing this problem has been the focus for this thesis.

A small number of (small scale) studies suggest that Vacuum-Assisted Suspension System (VASS) are more effective at conserving residuum volume than Suction Socket Suspension System (SSSS) (1-3). However, active (VASS) are costly, unlikely to be available to all amputees, not suitable for amputees with sensitive residuum skin, and difficult to fit, being sensitive to air-leakages. Therefore, this study has investigated whether modification of the SSSS by use of a suitable distal void volume in the socket, may reduce the in-socket air pressure fluctuations during gait, based on Boyle's law (the key novelty of this thesis), leading to improved conservation of residuum volume.

The main findings of this thesis will be discussed below.

Chapter 1 introduced this thesis. **Chapter 2** presented the background, the scientific rationale, aims and objectives of this thesis. This chapter began with describing lower limb loss, its levels, causes, prevalence and incidence, and amputees' quality of life. As the focus of this thesis is trans-tibial amputees, relevant prosthetic componentry was introduced, with a focus on vacuum-based and non-vacuum-based suspension systems.

The next part of the chapter focused on pistoning, the movement of the residuum within the socket, as a result of poor fit (34, 37, 45). Pistoning may lead to different problems, including injuries (51) and pain (46), and impact on the quality of life (46, 52). Pistoning has been characterised during static (2, 29) (*Figure 2.4*) and walking (21) conditions using a range of techniques, including radiological systems (X-ray and Computerised Tomography (CT)) (22, 53), photographic methods (34, 38), a

measuring tape (43), and an optical motion capture system (30, 31). Other methods include use of a noncontact photoelectric sensor (26), video-fluoroscopy (32), and a linear potentiometer (28). The magnitude of pistoning, in trans-tibial prosthetic sockets appears to be affected by the suspension system type, but the quality of the studies in this area is generally low (*Figure 2.10*). Only one study has measured the amount of pistoning during gait (21). In this study, the magnitude of pistoning during the swing phase was 2 mm, 3.3 mm, and 4.9 mm for the SSSS, magnetic-lock, and shuttle-lock systems respectively (21).

The impact of pistoning on gait was then discussed. Pistoning during the swing phase make the prosthetic limb longer than the sound limb. Thus, amputees adopt different strategies to clear their prosthetic foot during the swing phase. These strategies include pelvic obliquity on the prosthetic limb side (56), increasing the RoM of the sagittal prosthetic hip and knee joints and/or, vaulting gait on the sound limb side (58). Two studies linked the amount of pistoning to these compensatory strategies (21, 59). Eshraghi et al (2014) (21) and Gholizadeh et al (2014) (59) suggested that the differences in the peaks of the prosthetic knee joint flexion during the swing phase ($\sim 15^\circ$), between the SSSS and magnetic-lock system, could be related to quite small amounts of pistoning (1.3 mm). However, their conclusions were questionable.

As a reduction in residuum volume will lead to pistoning during gait and associated problems, the possible mechanisms leading to residuum volume changes (residuum volume fluctuations, or RVFs) were addressed. RVFs occur due to the body's fluid imbalance inside the residuum (64). The causes are complex, but may be classified as intrinsic factors, such as muscle atrophy (63), and extrinsic factors, such as in-socket air pressure (2). It is believed that changes to extracellular fluid is the primary cause of short-term RVFs (<1 day), while the long term changes (>1 day) may more likely be due to the changes in intracellular fluid volume (3, 64). To measure residuum volume, different techniques have been applied, including ultrasound imaging (69), radiological systems (Computerised Tomography (CT) and Magnetic Resonance Imaging (MRI)) (70, 71), a bio-impedance-based system (72), and 3-Dimensional (3D) optical surface scanner systems (73). Laser-based scanning (1) was shown in one study to have the highest repeatability (54), is easily portable, fast

to use, and has no side effects. However, methods to optimise the accuracy and repeatability of measurements when using a laser-based scanner system have not been used previously. Appendix C reports on a small study exploring these issues (Measuring the residuum volume using a laser-based scanner system).

A small number of studies were then reviewed, which reported on how long after doffing a socket, the residuum volume reaches a steady-state value (*Figure 2.21*) (64, 77). Zachariah et al (2004) (64) concluded that 8 minutes of resting following doffing the prosthesis is sufficient (64), while Sanders et al (2012) (77) reported that 4.3 minutes was sufficient (77). Very little research has been done on the amount of upright time needed to cause RVFs to occur, but one study showed that walking a distance of 200 meters (~ 4 to 5 minutes) was sufficient to show a measurable effect (64).

This section was followed by reviewing passive methods for managing the short-term reduction in residuum volume. These methods include: a) adding extra socks or a liner to (76) or doffing the prosthesis to allow recovery of the residuum volume (76, 77) and; b) using vacuum-based suspension systems, such as SSSS and VASS. However, the former methods can make the problem worse. By contrast, vacuum systems appear to reduce the reduction in residuum volume by creating a low in-socket air-pressure (2, 65). The passive system is easy to use, cosmetically appealing, and light weight. While the active system is higher cost and special training may be required to fit the system.

A few studies have compared the VASS and SSSS in terms of RVFs (*Figure 2.22*) (1-3). Board et al (2001) (2) showed that residuum volume increased, compared to V_{baseline} , by an average (range) of 3.7% (-1.6% to 8.5%) and decreased by 6.5% (-11.3% to -1.7%) with VASS and SSSS respectively, following 30 minutes of walking. In another study, Gerschutz et al (2010) (1) reported that residuum volume decreased, compared to V_{baseline} , by an average (range) of 0.4% (-0.3% to -0.5%) and 2.4% (-1.6% to -2.9%) with VASS and SSSS respectively. Sanders et al. (2011) (3) found that the residuum volume increased by an average (range) of 0.3% (-0.6% to 1.2%) and decreased by 0.1% (-0.5% to 0.3%) while using VASS and SSSS respectively (3). These studies differed in the methods used to measure residuum volume and protocols. A small number of studies also suggest that VASS can

improve gait (46, 78), comfort and self-reported prosthesis control (47) compared to the shuttle-lock system (78). VASS may also enhance residuum wound healing; possibly by increasing the blood supply in the residuum due to vacuum pressure (1, 47). Therefore, there is some evidence that the VASS can reduce the reduction in residuum volume during upright mobility, maintain residuum-socket fit and hence, decrease the amount of pistoning, subsequently, reducing pain and injuries.

Based on the discussion above, the aims and objectives of this thesis were presented, which were to: 1) Design and build a test prosthesis that allow participants to be tested walking with a SSSS, a modified SSSS, and a VASS; 2) Use the new prosthesis to compare the performance of the SSSS, modified SSSS, and VASS in terms of maintenance of residuum volume, comfort, and gait kinematics and Ground Reaction Forces (GRFs).

Chapter 3 reported the design of the Instrumented Trans-tibial Prosthesis (ITTP). Specifically, the aims of this chapter were to 1) estimate the distal void volume that, when introduced would significantly reduce the in-socket air pressure fluctuations while walking; 2) design a test-socket based on the finding in 1; 3) define the components of the ITTP and; 4) estimate the minimum residuum-ground clearance to allow for full assembly of the ITTP.

To calculate the volume, the typical magnitude of pistoning seen during gait was first found from the literature. Using 3D models of residuums, a simple cylinder model was developed, whose features included a user-defined initial volume. Assumptions were made with regard to pressure at a specified point in the gait cycle. Based on the cylinder model, together with the known pressure value, the effects of different initial volumes on pressure fluctuations during gait were calculated. A suitable distal void volume (additional 100 ml) was selected based on these results (*Figure 3.4*). Subsequently, the geometry of a removable plug allowing for the socket to be configured with a large or small distal void was defined (*Figure 3.5*). Based on the selected initial distal void volume, a test-socket was designed (*Figure 3.7*). Finally, the components of the ITTP were defined and the minimum residuum-ground clearance (27 cm) between the residuum and floor during upright standing was estimated. This was used to define inclusion criteria for the subsequent study (*Figure 3.9*).

Chapter 4 reported a within-day repeatability study of residuum volume, and gait kinematics and GRFs in trans-tibial amputees.

Following ethical approval from the University of Salford (Appendix B.1), five traumatic unilateral trans-tibial amputees took part in this study. Data were collected in the gait lab of the Brian Blatchford Building. Reflective flat targets, were placed on the silicone liner to measure the residuum volume using a laser-based scanner system. Spherical reflective markers were attached to allow capture of pelvis and lower limbs kinematics. Participants walked ~20 times along the length of laboratory at self-selected speed while gait kinematics and GRFs data were collected using optical motion capture and force plates systems respectively. The spherical markers were then removed, replaced and participants repeated the 20 walks. Participants then sat down, removed the socket while keeping the liner donned, and the volume of their residuum plus liner was measured five times over 20 minutes. Finally, the markers were removed and the participant re-donned his prosthesis.

The repeatability of residuum volume measurements was estimated using the Coefficient of Variation (CV) and expressed as a percentage for each participant. The mean of all of the participants' results were then calculated. The Intra-class Correlation Coefficient (ICC) and Standard Error of Measurement (SEM) were calculated to assess the repeatability of the gait kinematics and GRFs. Also, the Minimal Detectable Differences (MDD) in these gait parameters were estimated to define the minimum amount of changes in the gait kinematics and GRFs of the future study that must be achieved to reflect true differences due to interventions, not due to error, such as markers placements (93).

The results of measuring the residuum volume using a laser-based scanner system were highly repeatable ($CV < 1\%$) (*Table 4.2*). The repeatability of gait kinematics and GRFs was excellent ($0.93 < ICC < 1.0$) (*Table 4.3*). The SEM and MDD values were ($0.0^\circ < SEM < 1.0^\circ$) and ($0.0^\circ < MDD < 2.7^\circ$) respectively, for the gait kinematics and GRFs (*Table 4.3*). In one participant, even after 25 minutes of rest following doffing of the socket (but not the liner), it appeared that steady state volume had not been reached, raising questions over the 4.3 minutes settling time proposed by Sanders et al (2012) (77). These results supported the use of the laser-based scanner system in the following study. Further studies to assess the inter-

rather repeatability of residuum volume measurements using these systems are recommended.

Chapter 5 reported on the piloting of the protocol for the main study, reported in Chapter 6. One participant was recruited from the pool of professional amputees that participate in Salford's undergraduate Prosthetics and Orthotics (P&O) programme. This participant did not self-report RVFs and/or pistoning problems, thereby not reducing the pool of potential participants for the main study.

Two visits to the University of Salford were required to complete the study. The first visit was for casting and measurements (*Figure 5.1*). The second visit was for the ITTP fitting and data collection (*Figure 5.8*). Data of RVFs, comfort, pistoning, and gait kinematics and GRFs were collected through a repeated measures experiment across the three test-conditions (*Table 5.1*).

Gait kinematics and GRFs were collected and analysed without any problems, across the 3 test-conditions. Comfort assessment was also straightforward. Pistoning during gait proved difficult to capture from the liner-mounted paper retro-reflective markers. The possible reasons for this were: 1) the paper markers reduced the reflected light back to the cameras; 2) the transparent thermoplastic material limited the visibility of the paper markers to the cameras and; 3) the cameras in the Brian Blatchford lab are in fixed positions which were less than ideal for capturing the markers on the liner.

Therefore, it was decided that pistoning assessment was not feasible for the main study and the required amendments were applied to the main study protocol (*Figure 5.10*). It was also identified that testing the Limb-Logic communicator (vacuum pump) prior to each data collection day would be essential.

Chapter 6 had two primary aims. The first aim was to build a test prosthesis that allow participants to be tested while walking with a SSSS, a modified SSSS, and a VASS. The second aim was to use the new prosthesis to compare the performance of the SSSS, modified SSSS, and VASS in terms of maintenance of residuum volume, comfort and, gait kinematics and GRFs.

Following ethical approvals from the University of Salford (UoS) (Appendix F.1) and the National Health Service (NHS) (Appendix F.2), five amputee participants took part in this study (*Table 6.1*). They were recruited from the professional amputees database employed within Salford's undergraduate P&O programme and through the NHS (*Figure 6.14*). Two visits to the University of Salford were required for each participant to complete the study, as explained above. Data of residuum volume, comfort, and gait kinematics and GRFs were analysed. Results of RVFs and comfort were then tested statistically (*Figure 6.3*).

The results showed that the residuum volume decreased, relative to the V_{baseline} , by an average \pm SD of $4.2\% \pm 2.8\%$ for SSSS, $1.4\% \pm 1.4\%$ for modified SSSS, and $1.6\% \pm 1.1\%$ for VASS (*Figure 6.5*). Post-hoc Wilcoxon matched pairs, with a Bonferroni adjustment ($Z \geq -2.023$, $P \geq 0.063$) indicated that the RVFs mean ranks did not differ across the test-conditions ($P > 0.0167$) (Appendix H, *Table H.3*). Also, the comfort (out of 10) average \pm SD was 7.6 ± 2.1 for SSSS, 6.4 ± 2.1 for modified SSSS, and 7.2 ± 1.8 for VASS (*Figure 6.7*). The one-way repeated measures ANOVA ($F = 1.155$, $P > 0.363$) indicated that the comfort mean ranks did not differ significantly across the three test-conditions (Appendix H, *Table H.5*). Finally, the gait kinematics and resultant GRFs varied between participants (*Figure 6.8* to *Figure 6.11*) and within participants (Appendix I), making it difficult to draw conclusions from these data.

In conclusion, there is some evidence that the performance of SSSS, in terms of reducing the reduction in residuum volume, may be achieved through the introduction of a distal void volume (additional ~ 100 ml). However, a larger study would be needed to confirm this.

7.2. Future work

1. Larger studies

One of the most common limitations across the studies in the area of prosthetics is the low number of participants. Several of the studies of pistoning and RVFs involved only a single case study (1, 22-27). In this thesis, 5 amputees participated in the main study (Chapter 6). The low number of participants may have contributed to the need to use less powerful, non-parametric statistics, which led to no significant differences being found between conditions. Therefore, this study could be considered as a preliminary study. Applying the same protocol to a larger sample size of amputees may lead to a more conclusive outcome.

2. The effects of RVFs on pistoning and gait parameters

There are only 2 papers linking the amount of pistoning to gait parameters (21, 59). Also, to the author's knowledge, no study has linked the RVFs to the amount of pistoning and gait parameters. Further work is needed in this area.

3. In-socket air-pressure profile data

A few small studies have suggested that a decrease the in-socket air pressure may help to reduce the reduction in residuum volume (1-3). However, how the pressure profile might compare between the vacuum-based suspension systems and how the different features of the pressure profile (peak, range, mean etc) may impact on maintaining the residuum, are also not known. As this study did not manage to collect pressure data, due to problems with the limb-logic Communicator, future studies are needed to address this issue (In-socket air-pressure profile data).

7.3. Thesis limitations

The limitations over this thesis can be summarised as follows:

1. Number of participants

The low number of participants was the main limitation in the main study (Chapter 6). This led to a low statistical power (no significant differences being found across the test-conditions) and hence, difficulties to generalise the results from this study.

2. In-socket air pressure profile data

Obtaining the in-socket air-pressure profile data was difficult, due to problems with the limb-logic Communicator⁵⁶. The sensor measured gauge air pressure sensor and was unable to detect below atmospheric pressures and the response of the vacuum pump sensor appears to be rather slow. This made interpreting the residuum volume changes based on the in-socket air pressure profile data (peak, range, mean etc) impossible. Further work is needed to properly understand this issue.

3. Pistoning assessment

Pistoning movement during proved to be impossible to assess from the liner-mounted paper retro-reflective markers. Thus, it was impossible to link the residuum volume change with the gait compensatory mechanisms as a result of pistoning across the test-conditions.

⁵⁶ Appendix J: The investigation into obtaining in-socket air pressure profile from the Limb-Logic Communicator

7.4. Novel work in the thesis

The original contributions of this work can be summarised as follows:

1. An accurate and repeatable method for measuring the residuum volume using a laser-based scanner system (Appendix C);
2. The first study to propose that the performance of the SSSS may be improved by suitable selection of initial distal void volume in order to reduce the in-socket air pressure during walking (based on Boyle's law) and hence, reduce the reduction in residuum volume (Chapter 3) and;
3. The first study to compare the performance of the SSSS, modified SSSS, and VASS in terms of maintenance of residuum volume, comfort, and gait kinematics and GRFs (Chapter 6).

Appendices

Appendix A: Estimating the distal void volume between residuum and socket based on typical prosthetist's practice

A.1. Aims

The aim of this experiment was to estimate the typical range of distal void volumes between residuum and socket, based on current clinical practice.

A.2. Methods

The methods involved the following steps:

- a) Identification of typical values used by prosthetists in extending scans of residuums to produce comfortable sockets and;
- b) Using the data from step (a) to identify the typical range of distal void volumes found in clinical sockets.

A.2.1. Identification of typical values used by prosthetists in extending scans of residuums to produce comfortable sockets

An informal survey of colleagues in the Prosthetics and Orthotics Department and former colleagues in Jordan and Saudi Arabia was carried out to establish the typical amount of plaster added to the distal end of a mould during the socket casting/fabrication process, in order to produce a comfortable socket. A consensus was reached that during the plaster modification process prosthetists typically add between 0.5 cm and 1 cm to the distal end of trans-tibial plaster moulds. However, in cases where a silicon liner is to be used for a trans-tibial amputee the prosthetist may not add any plaster at the distal end of the mould to ensure the liner reaches the bottom of the socket. Hence, the estimated range of extensions to the distal end lies between 0 cm and 1 cm for both trans-tibial residuums.

A.2.2. Identification the typical range of distal void volumes found in clinical sockets

Data of residuums of seven trans-tibial amputees were chosen randomly from the database of previously scanned residuums taken as part of prosthetics and orthotics training at the University of Salford. The data were already anonymised and hence no ethical application was required for this experiment.

OMEGA Tracer software⁵⁷ (Laser-based scanner system) was used to estimate the range of typical distal void volumes between the residuum and socket as follows (*Figure A. 1*):

The user selected, and then loaded a scanned residuum of trans-tibial amputee from the scanner system database. The proximal plane defining the upper bound of the residuum had been defined earlier and hence the model was bounded by this plane and the surface of the residuum.

- a) The user selected the option “Extend by adding material” from the tool bar. The user entered 1 cm;
- b) Following guidance from the scanner system manufacturer with regard to elongation of models, the user identified two transverse planes through the model located at approximately 4 cm and 8 cm superior to the distal end of the model, in a region where the shape of the residuum was approximately prismatic. The scanner system then applied an elongation of 1cm to the model between these two planes, thereby extending the total length of the model by 1 cm;
- c) The user then selected the option “Volume change” from the toolbar to calculate the model volume before and after the extension process. The difference between these two volumes was considered the distal void volume (*Figure A. 1*).

⁵⁷ Willow Wood Company, Ohio, USA

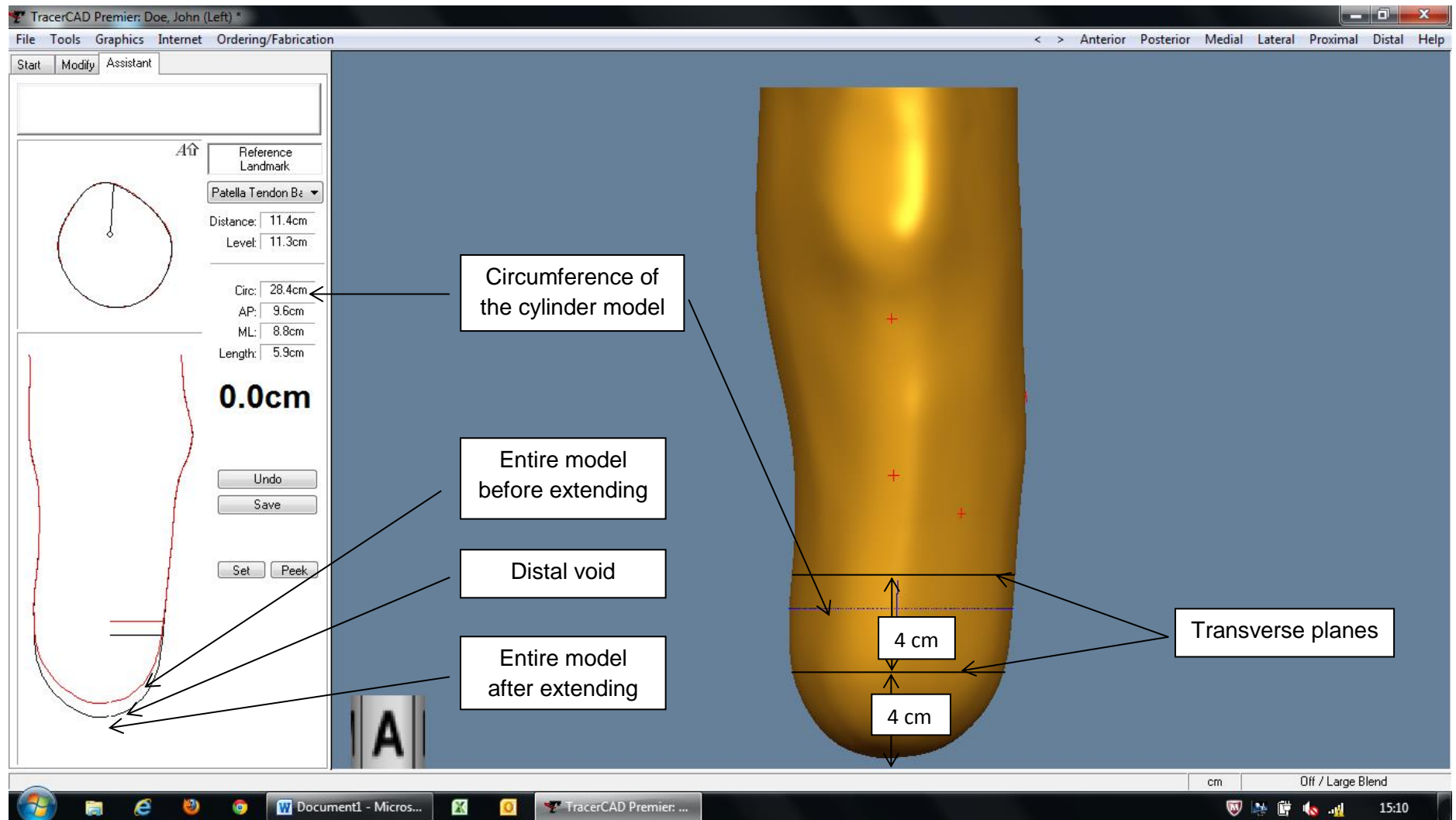


Figure A. 1: A scanned residuum of trans-tibial amputee after applying 1 cm extension (Anterior view).

A.3. Results

Table A.1 shows the calculated distal void volumes between residuums and trans-tibial sockets.

Table A.1: The distal void volumes between trans-tibial residuums with and without 1 cm elongation, based on a laser-based scanner system.

Number	Volume (ml)		
	Entire model before extending	Entire model after extending	Distal void
1	2415	2485	70
2	1739	1810	71
3	1515	1556	41
4	2715	2780	65
5	1336	1397	61
6	1727	1774	47
7	1792	1855	63
Mean (Range)	1891.3 (1336_2715)	1951 (1397_2780)	59.7 (41-71)

A.4. Discussion and conclusions

This experiment has demonstrated an approach to using a laser-based scanner system to calculate the distal void volume between the residuum and socket. The typical values used by prosthetists in extending the moulds during the modification and hence produce comfortable sockets were found to be typically between 0 cm and 1 cm for trans-tibial socket.

As shown in Table A.1, after the models were extended by 1 cm the additional volume was found to be approximately 60 ml. This value was considered when estimating the desired initial distal void volume in (Chapter 3: Instrumented Trans-tibial Prosthesis (ITTP)).

The calculations below show a strong agreement between the distal void volume calculated from the laser-based scanner system and approximations based on a cylinder model.

The user interrogated the scanner system to provide a value for model circumference (C_{mid}) at a location approximately midway between the two transverse planes. By fitting a circle to the circumference data, a radius value was calculated (R), as follows:

$$R = C_{mid} / 2 * \pi \quad (8)$$

Then, the area of the cylinder model ($A_{cylinder}$) was calculated by using the following formula:

$$A_{cylinder} = \pi * R^2 \quad (9)$$

The height of the cylinder ($H_{cylinder}$) was considered as the amount of extension (1 cm). The volume of the cylinder model ($V_{cylinder}$) was calculated based on R and $A_{cylinder}$ using formula (10). The results were rounded to nearest 1 ml.

$$V_{cylinder} = A_{cylinder} * H_{cylinder} \quad (10)$$

The process was repeated for the selected scanned of trans-tibial residuums. For an additional check of the volume value generated by the laser-based scanner system; the first trans-tibial model was shortened by 1 cm after a 1 cm extension was applied. Thus, the original volume of the model was compared before extension and after shortening.

Table A.2: Comparison of distal void volumes calculated by laser-based scanner system and estimated based on cylindrical model.

Number	Laser-based scanner system (ml)	Cylindrical model (ml)
1	70	71
2	71	69
3	41	45
4	65	66
5	61	63
6	47	51
7	63	64
Mean (Range)	59.7 (41-71)	61.3 (45_71)

Figure A.2 shows the correlation of the distal void volumes based on the laser-based scanner system and calculations.

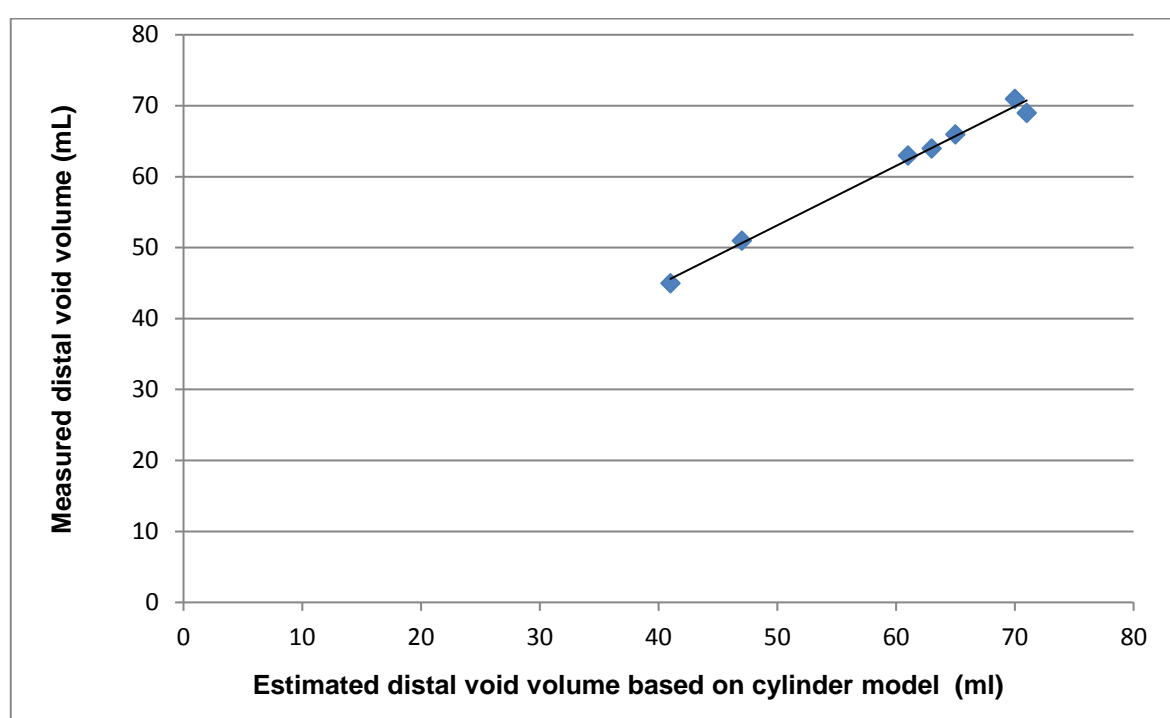


Figure A.2: Correlation of the distal void volumes between residuums and trans-tibial sockets, with 1 cm elongation, based on a laser-based scanner system and cylinder model estimations.

The first trans-tibial model was shortened by 1 cm after a 1 cm extension was applied for an additional check of the volume value generated by the scanner system. The original volume of the model was before extension 2415 ml and after shortening 2416 ml. The difference was only 1 ml.

Appendix B: Within-day repeatability of residuum volume measurement and gait parameters of traumatic trans-tibial amputees (Chapter 4)

Appendix B.1: Ethical Approval from the University of Salford



University of
Salford
MANCHESTER

Research, Innovation and Academic
Engagement Ethical Approval Panel

Research Centres Support Team
G0.3 Joule House
University of Salford
M5 4WT

T +44(0)161 295 2280

www.salford.ac.uk/

2 November 2015

Dear Huthaifa,

RE: ETHICS APPLICATION HSCR 15-119 – Within-day test-retest reliability of residuum volume and gait parameters of trans-tibial amputees.

Based on the information you provided, I am pleased to inform you that application HSCR15-119 has been approved.

If there are any changes to the project and/ or its methodology, please inform the Panel as soon as possible by contacting Health-ResearchEthics@salford.ac.uk

Yours sincerely,



Sue McAndrew
Chair of the Research Ethics Panel

Appendix B.2: Participant Information Sheet

Participant Information Sheet

Within-day test-retest reliability of residuum volume and gait parameters of trans-tibial amputees

I would like to invite you to take part in a research study at the University of Salford. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. You can ask questions about anything you read is not clear or would like more information. Please take time to decide whether or not to take part.

What is the purpose of the study?

Amputees often experience problems resulting from the change in volume of their residual limb over the course of a day. This reliability study is being carried out prior to a subsequent main study which will look at a new method for reducing the changes in limb volume seen by many amputees. As part of the main study we will need to measure both limb volume, and movements during walking. Thus, to have confidence in our interpretation of the main study results, it is necessary to carry out a reliability study on the two key measurement techniques: 1) Measurement of residual limb volume and; 2) Measurement of movements during gait. Therefore, the purpose of this study is to assess the reliability for within-day test-retest to estimate the minimal difference in key outcome measures which can be attributed to measurement error.

Why have I been invited?

In the main study we will be interested in studying how to improve the day-day fluctuations in residual limb volume in people with trans-tibial amputation. You have been invited to participate in this reliability study as our records suggest you are someone with this level of amputation.

Do I have to take part?

It is up to you to decide to take part or not. After reading this information sheet, we will explain the study to you and go through this information sheet. If you are still willing to take part we will ask you to sign a consent form. However, if you do not wish to take part then you do not have to. You can also withdraw from the study once you have consented at any time, without giving a reason for this.

What will happen to me if I participate in this study?

If you decide to take part, you will be required to come to the movement laboratory, in Allerton building, School of Health Sciences at the University of Salford for one visit only. During the visit will give you an opportunity to ask questions, before inviting you to sign the consent form. If you consent, we will carry out a small number of measurements. First, we will attach reflective markers on your lower limbs as shown in *Figure 1*. Then, you will be asked to walk along the laboratory walkway up to 10 times to collect your movement data using cameras. After that, the markers will be removed and you can rest. Next, we will repeat this measurement after attaching the markers again. We will remove the markers and then ask you to remove your prosthesis and sit while we take a measurement of your residual limb volume using a system you may have seen used by your prosthetist. The system we will use is

shown in *Figure 2* below. Measurements of your residual limb volume will repeat seven times over the course of about 20 minutes. Finally, we will invite you to put on your prosthesis and the testing will be completed. The duration for this single visit will be about one hour 30 minutes.



Figure 1: Person with reflective markers attached.

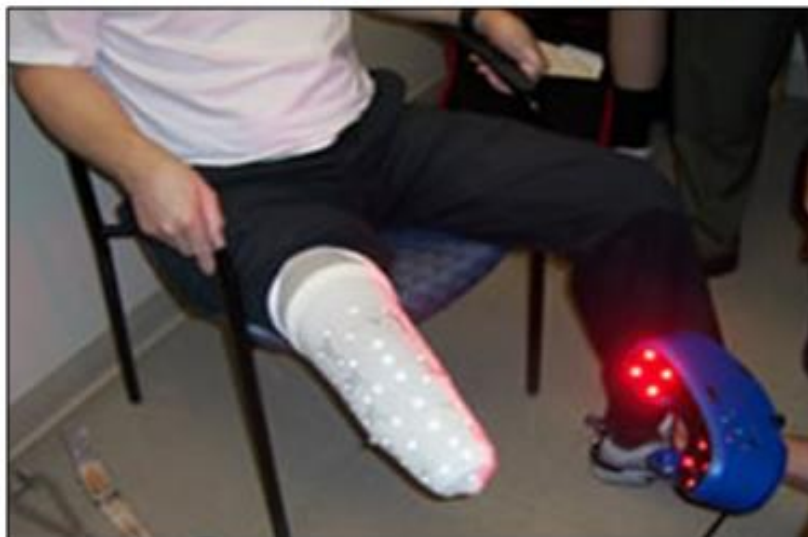


Figure 2: Scanning an amputee's residuum by a hand scanner.

What expenses and payment will be available to me?

In case you need transportation for your visits to the university, the researcher will arrange and pay for a taxi from home and back again. Alternatively, you can make your own transport arrangements, and we will refund any reasonable costs that you incur. In recognition of your efforts, the University of Salford will offer you a £20 gift voucher for participation in the study.

What will I have to do before the testing at Salford?

You will not be asked to make any changes to your lifestyle before the testing at Salford.

What are the possible disadvantages and risks of taking part?

We will be asking you to carry out everyday activities, such as walking. All tests will be carried out using standard measurement equipment. Therefore, we think the risks associated with taking part are very low.

What are the possible benefits of taking part?

There are no short-term personal benefits to you from participating, but the University of Salford will offer you a £20 gift voucher. However, this study will be very useful in helping us to progress towards finding a better way of managing limb volume fluctuations.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researcher, who will do his best to answer your question,

Researcher's name: Mr. Huthaifa Atallah

Contact number: 07769763776

Email: h.m.atallah@edu.salford.ac.uk

If you do not wish to discuss your complaint with the researcher, you can directly contact the study supervisor,

Supervisor's name: Professor Laurence Kenney

Contact number: 016129 52289

Email: L.P.J.Kenney@salford.ac.uk

Then you can contact the research and innovation (R&I) manager at University of Salford,

R&I manager's name: Dr Anish Kurien

Email: a.kurien@salford.ac.uk

Phone: 016129 55276

Will my taking part in this study be kept confidential?

All information which is collected about you during the study will be kept strictly confidential. Your name and address will be removed from your data, so it cannot be recognised. Movement data will be collected while you are walking with your own prosthesis and within your comfortable speed in the movement laboratory. Also, your residual volume will be measured using a hand-scanner while you are sitting on a chair (Please see Figure 2). Finally, all the collected data will be recorded and stored on a secure password-protected University of Salford desktop computer and research team member laptop. These data will not be accessible to anyone other

than the research team members. All these data will be disposed of securely after 5 years.

What will happen if I do not carry on with the study?

If you withdraw from the study, the researcher will need to use the data collected up to your withdrawal.

What will happen to the results of the research study?

The results will be written up in a report that will form part of a doctoral thesis. However, your data will only be included in this report if you sign the Participant Consent Form.

Who is organising and sponsoring the research?

The research is being organised and funded by the Centre of Health Sciences research, University of Salford, Salford, M6 6PU.

Who can be contacted for independent advice about participating in the study?

For independent advice about participating in the study, please contact:

Dr Anita Williams (Post Graduate Research Studies Director)

Phone: 0161 295 7027

E-mail: a.e.williams1@salford.ac.uk

Who can be contacted for further information?

For further information about the study procedures or treatments, or to withdraw from the study, please contact:

Mr Huthaifa Atallah (postgraduate student)

Centre for Health Sciences Research

School of Health Science

PO.34, Brian Blatchford Building

Frederick Road

University of Salford

Salford, M6 6PU

Mobile: 07769763776

E-mail: h.m.atallah@edu.salford.ac.uk

OR

Dr John Head (Lecturer in Prosthetics and Orthotics)

Centre for Health Sciences Research

School of Health Science

PO.47, Brian Blatchford Building

Frederick Road

University of Salford

Salford, M6 6PU

Phone: 01612952303

E-mail: J.Head@salford.ac.uk

Thank you for the time you spent reading this Participant Information Sheet

Appendix B.3: Participant Invitation Letter

Participant Invitation letter

Mr. Huthaifa Atallah (postgraduate student)
Centre for Health Sciences Research
School of Health Science
PO.34, Brian Blatchford Building
Frederick Road
University of Salford
Salford, M6 6PU
Mobile: 07769763776
E-mail: h.m.atallah@edu.salford.ac.uk

Dear Sir/Madam

I am writing to invite you to consider participating in a pilot research study at the University of Salford. This reliability study is being carried out prior to a subsequent larger study which will look at a new method for reducing the fluctuations in residual limb volume seen by many amputees. As the main study will need to measure both residual limb volume and gait movements and forces; the focus for this project is to study the reliability of these measurements.


For further information about this study and what it will involve; please read carefully the attached (**Participant Information Sheet**). If there is any ambiguity or unclear, or you need further information. Please do not hesitate to contact the researcher, Mr. Huthaifa Atallah, whose details are given both above and at the end of the patient information sheet. Also, you can contact the study supervisor, Dr. John Head, whose details are given in the Participant Information Sheet.

Finally, if you are interested in taking part in the study, please contact the researcher, Mr. Huthaifa Atallah by email, phone, or in person, whose details are given both above and at the end of the patient information sheet. If you decide to participate, the University of Salford will cover your travel expenses and offer you a £20 gift voucher in recognition of your efforts.

Thank you for reading this letter.

Best regards,
Huthaifa Atallah (The researcher)

Appendix B.4: Participant Consent Form

		
<h3><u>Participant Consent Form</u></h3>		
Participant number:		
Date:		
<u>Title of study:</u>		
Within-day test-retest reliability of residuum volume and gait parameters of trans-tibial amputees		
<u>Name of researcher:</u>		
Mr. Huthaifa Atallah, postgraduate student, Center for Rehabilitation and Human Performance Research (CRHPR), University of Salford, Salford, M6 6PU.		
1. I confirm that I have read and understood the Patient Information Sheet (V1 22.9.2015) for the above study and have had the opportunity to ask questions.		<input type="checkbox"/>
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected.		<input type="checkbox"/>
3. I understand that all my data are secured, and that no one can access to my data except research team members.		<input type="checkbox"/>
4. I understand that just the anonymised data will be published in the research.		<input type="checkbox"/>
5. I understand that I can withdraw from the study anytime, and the researcher will need to use the data collected up to my withdrawal.		<input type="checkbox"/>
----- Name of patient	----- Date	----- Signature
----- Name of person Taking consent (If different from Researcher)	----- Date	----- Signature
----- Name of researcher	----- Date	----- Signature
PCF V 1.0 22/09/2015		

Appendix C: Measuring the residuum volume using a laser-based scanner system

C.1. Aims

The aims of this experiment were to:

- Demonstrate calculation of residuum volume based on a laser-based scanner system and;
- Investigate the alignment effects of a scanned residuum on the volume calculation based on laser-based scanner system data and hence identify the optimal alignment.

C.2. Methods

OMEGA Tracer⁵⁸, a laser-based scanner system, was used in this study to investigate accuracy of residuum volume estimation. A residuum model was selected arbitrary from the Prosthetic and Orthotic workshop. This residuum model was fitted with a silicon liner. Two vertical lines were then drawn on the anterior and lateral sides of the liner, approximately at the middle (*Figure C. 1*). Adhesive retro-reflective paper markers (Targets) were attached to the liner to enable the scanner to capture the geometry of the model. Two targets were attached proximally and distally on each vertical line, later used to align the 3D model (*Figure C. 1*). The two targets in each pair were as widely spaced apart as possible. The proximal target on the anterior vertical line was considered as a reference point to define the proximal transverse plane during the calculations of residuum volume.

⁵⁸ Willow Wood Company, Ohio, USA

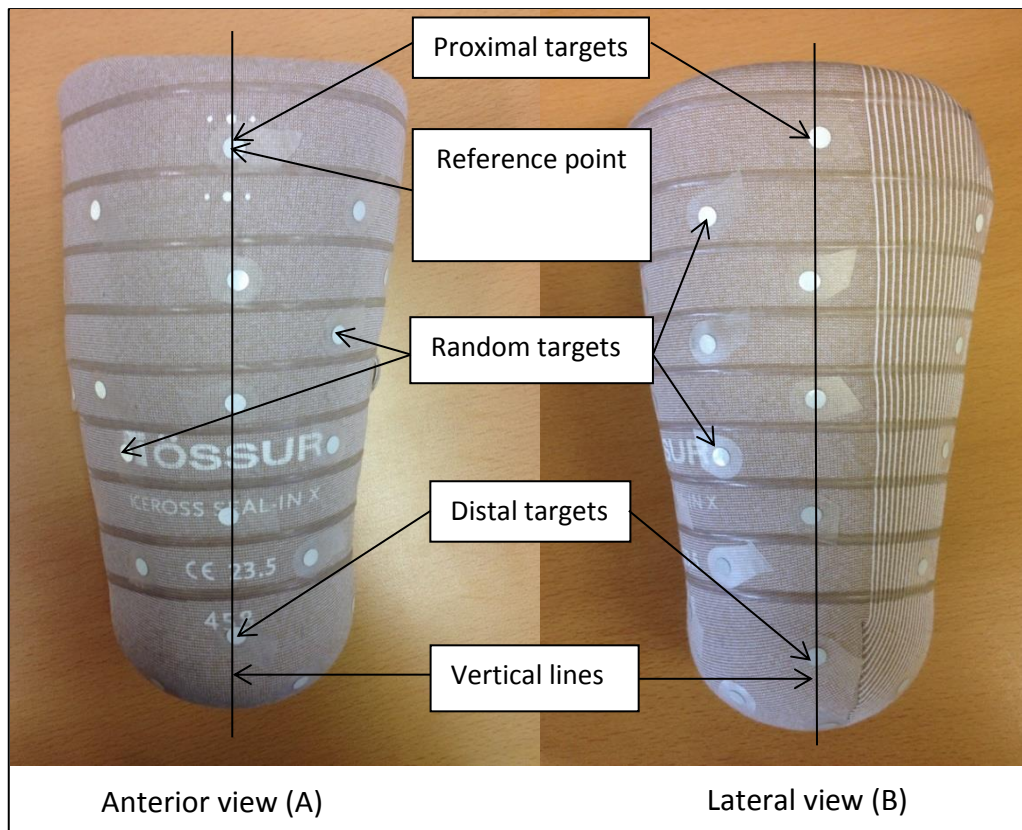


Figure C. 1: Residuum model fitted with a silicon liner, shown in anterior (A) and lateral (B) views.

The residuum model was scanned using the OMEGA Tracer system. Once the scanning finished, the residuum volume was calculated from the created 3-dimensional model under two different (user-selected) alignment-conditions:

- 1) Condition A: Frontal and sagittal plane alignments (Anterior and lateral views) and;
- 2) Condition B: Two sagittal plane alignments (Lateral view only).

A goniometer set at 90° was placed onto the monitor to align the 3D model through the proximal and distal targets in frontal and sagittal planes. Finally, the volume reading at the reference point was considered.

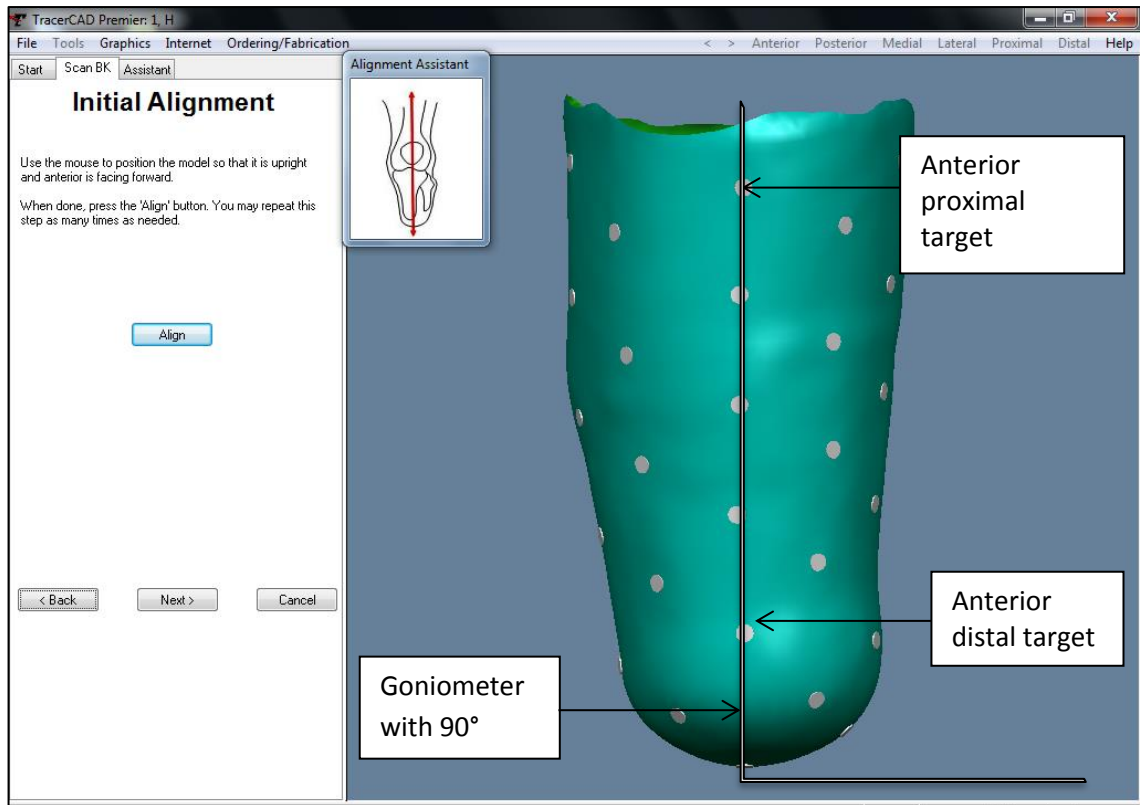


Figure C. 2: Using anterior proximal and distal targets to align the 3D model in the frontal plane with 0° (Anterior view). (The first alignment option in scanner software)

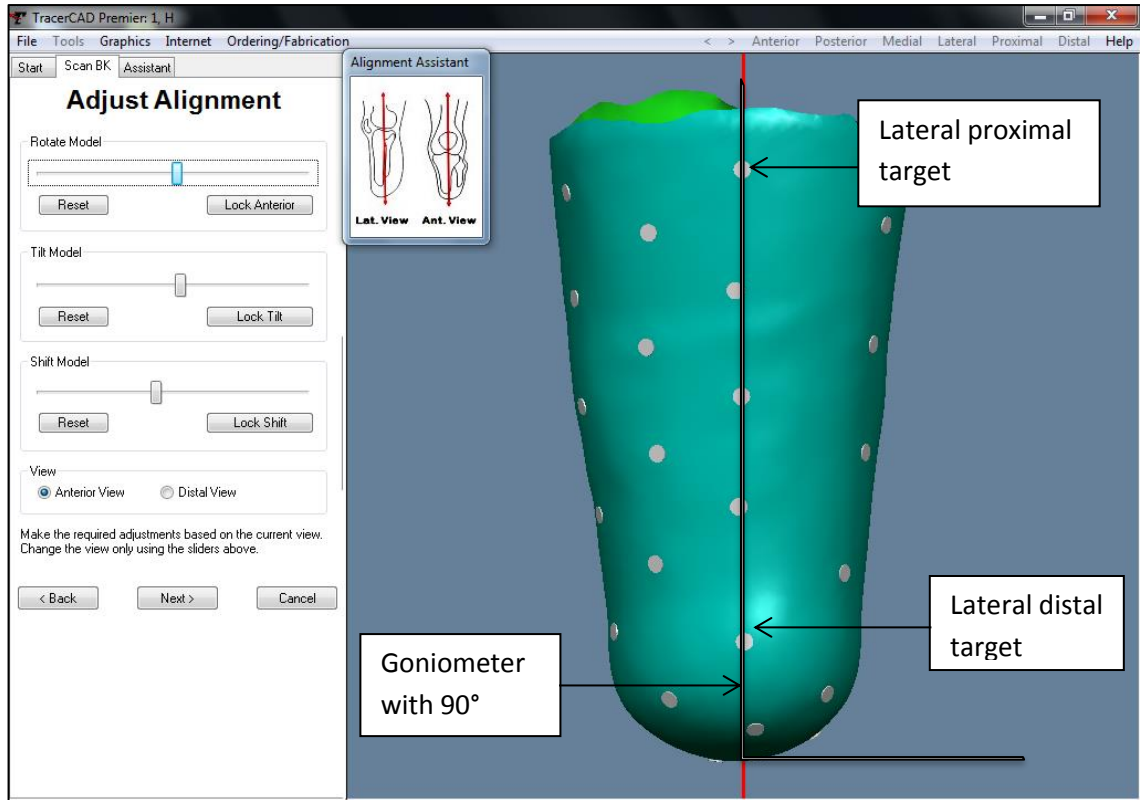


Figure C. 3: Using lateral proximal and distal targets to align the 3D model in the sagittal plane with 0° (Lateral view). (The second alignment option in scanner software)

To assess repeatability, the process was repeated 20 times for the same residuum model. The residuum volume results were rounded to nearest 1 ml. Standard error of mean (SEmean) was calculated for each alignment-condition using the formula (11). The calculations of mean, SD, and SEmean were rounded to nearest 0.1 ml.

$$SEmean = \frac{SD}{\sqrt{n}} \quad (11)$$

Where “SD” is the standard deviation and “n” is the number of scans.

In order to assess the accuracy of the residuum volume calculated from the laser-based scanner system the results were compared with the water mass method (‘gold standard’ method). For this purpose, two perpendicular lines were drawn on the same residuum model, already used in the previous part. A plastic bowl was

placed on a plastic-covered digital scale⁵⁹ (AX4202/E model, range (0.5 – 4220) g, and 0.01 g resolution) and the scale zeroed. The bowl was then filled with water to the brim and the mass recorded. The residuum model was then immersed in the water to the anterior reference point, keeping the lateral vertical line approximately vertical, thereby displacing the volume of water corresponding to the model volume and the residuum model was then removed. The mass was taken again. The difference between the two readings were then converted to volume, based on the density of water, and this was taken as the model volume. This procedure was repeated five times.

C.3. Results

Repeatability of volume measurement using the OMEGA Tracer system.

Residuum model volume (Mean \pm SD) using the alignment-conditions A and B were 1429.6 ± 12.4 ml and 1416 ± 8.5 ml respectively. The 2 SEmean of residuum volume under the alignment-conditions A and B were 5.5 ml and 3.8 ml respectively.

The residuum volume based on the water mass method was 1450.4 ± 15.2 ml.

C.4. Discussion

This experiment has demonstrated the measuring of residuum volume using laser-based scanner systems. Residuum model volume was measured under 2 different alignment-conditions of its 3D model. The SEmean for condition B (5.5 ml) was lower than in condition A (3.8 ml). Also, the error for condition B (2.4%) was higher than in condition A (1.4%). Thus, using lateral proximal and distal targets to align the 3D model in the sagittal plane with 0° (condition B) will be the option while measuring the residuum volume using a laser-based scanner system.

⁵⁹ Ohaus Corporation, New Jersey, USA

Appendix D: Using V3D Software to analyse and report gait parameters

Gait kinematics data were processed using Vicon Nexus Software for markers labelling. Gait kinematics and GRFs files were then exported to Visual 3-Dimensional (V3D) software⁶⁰ as coordinate 3D (C3D) files to manage, analyse, and report the related results. A model was built as shown in *Figure D.1* and *Table D.1*. The study pipeline was then created as illustrated in *Table D.2*.

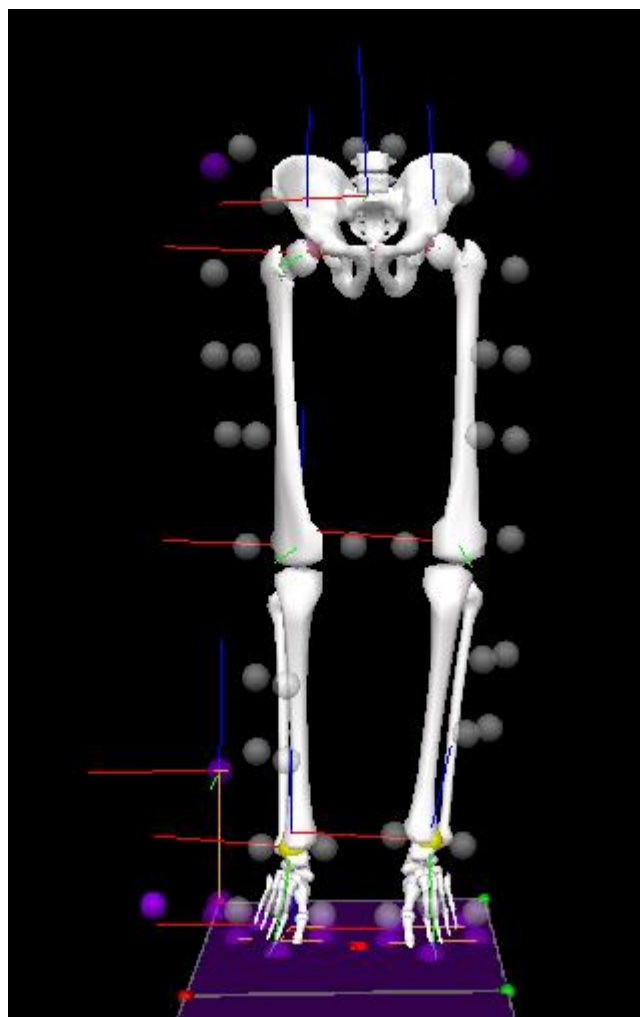


Figure D.1: V3D Study model.

⁶⁰ C-motion Incorporation, Germantown, USA

Table D.1: V3D study model, with seven main segments.

Segment name	Segment type	Segment markers
Pelvis	Coda ⁶¹	<ul style="list-style-type: none"> • Anterior: right and left anterior – superior iliac spines • Posterior: right and left posterior – superior iliac spines
Right and left thigh	V3D	<ul style="list-style-type: none"> • Joint centre: hip joint (*) • Distal: medial and lateral knee epicondyles
Right and left shank	V3D	<ul style="list-style-type: none"> • Proximal: medial and lateral knee epicondyles • Distal: medial and lateral ankle malleolus
Right and left foot	V3D	<ul style="list-style-type: none"> • Proximal: medial and lateral ankle malleolus • Distal: first and fifth foot metatarsals

(*) The hip joint centre was predicted based on the distance of the markers onto the right and left anterior – superior iliac spine (14% medially, 30% distally, and 22% posteriorly) (100).

⁶¹ Coda pelvis segment can be created based on the markers on the right and left anterior – superior and posterior – superior iliac spines. While, V3D pelvis segment can be created based on the markers onto the iliac crests or the greater trochanters. However, the former segment type can be only selected for the pelvis.

Table D.2: V3D pipeline with eight automatic sequential processing commands.

Command number	Command	Command preview
1	File open	To open the walking files
2	Create hybrid model	To open the standing file
3	Apply model template	To open the study model file (see <i>Figure D.1</i>)
4	Assign model file	To select the participant's trials and apply it into the study model
5	Interpolate	To fill any trajectory gaps (up to a maximum of 10 consecutive frames)
6	Low-pass filter	To digitally filter any high frequency noise by applying a 4th order low pass Butterworth filter with a cut-off frequency of 6Hz for kinematics data (90)
7	Low-pass filter	To digitally filter any high frequency noise by applying a 4th order low pass Butterworth filter with a cut-off frequency of 25Hz for Ground Reaction Forces (GRFs) data (90)
8	Automatic gait events	To show and edit events' dialog for each walking trial while using automatic labelling at heel strike (foot on) and toe off (foot off)

Thereafter, a preliminary report was obtained from V3D software for each participant, as shown in the *Table D.3*.

Table D.3: V3D report.

Page number	Page title	Page preview
1	Subject information	The descriptive information for each participant (ID, height, weight, sex, date of birth, test date, diagnosis, and test conditions)
2	Kinematics results	Kinematics data were calculated through normalising the gait cycle from 0% to 100%. All joint angles were calculated using the right-handed coordinate system rule. Pelvic obliquity was defined by the angle between the X-axis of the pelvis and the X-axis of the Global Coordinate System (GCS) (Frontal plane). Joint angles for the hip, knee, and ankle were defined by the angle between the distal segment and the proximal segment.
3	GRFs results	GRFs were normalised to the body weight using default normalisation option from the model based data, and to the stance phase (from 0% to 100%).

Finally, the primary results were exported as TXT files to Microsoft Excel Software to identify the RoM of the gait kinematics and the peaks of GRFs.

Appendix E: Testing the Limb-Logic Communicator integrated with a test-prosthesis

E.1. Aims

The aims of this experiment were to:

- Identify means of reducing any air-leakage, which may exist and;
- Compare the effects of the air-leakage from different locations on the operation of Limb-Logic Communicator.

E.2. Methods

A Seal-In liner was fitted in the test-socket and sealed using adhesive tape placed around the outside of the test-socket (*Figure E.1*). The Limb-Logic communicator (vacuum pump) was managed through the Limb-Logic software installed in a laptop. Standard mode was selected and a target vacuum (set point 14 inHg and moving range 4 inHg) defined. The vacuum pump was unable to create the desired in-socket negative pressure caused by the vacuum and this appeared to be due to an air-leakage. To manage this problem; the possible locations of the air-leakage were defined as shown in *Figure E.1*. These locations were: the urethane sleeve suspension, manual expulsion valve (valve) and/or socket-valve interface, and socket-pump interface. The possible locations of the air-leakage were addressed as explained below and in *Table E.1*.

The pump was run under 4 different conditions:

1. Condition A: Uncovered valve and socket-valve interface, and without extra rubber seal between the socket and pump;
2. Condition B: Covered valve and socket-valve interface;
3. Condition C: Applying extra rubber seal between the socket and vacuum pump and;
4. Condition D: Covered valve and socket-valve interface, and an extra rubber seal between the socket and pump.

E.3. Results

Figure E.1 shows a sealed test-socket integrated with Limb-Logic communicator.

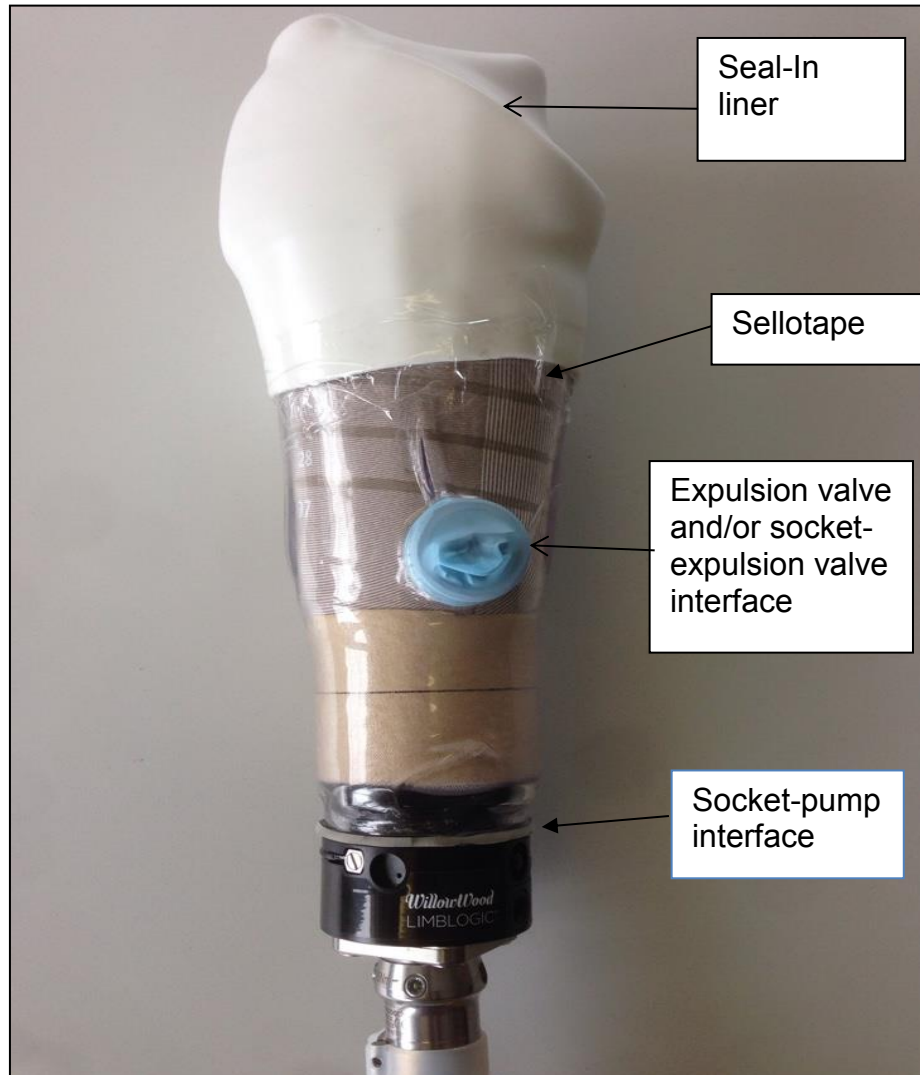


Figure E.1: A sealed test-socket integrated with Limb-Logic Communicator.

Table E.1 illustrates the possible locations of the air-leakage and their potential solutions.

Table E.1: Locations of the air-leakage and potential solutions.

Possible air-leakage location	How addressed
Urethane sleeve suspension	<ul style="list-style-type: none"> • Cover the proximal and distal edges of the urethane sleeve suspension using sellotape
Expulsion valve and/or socket-expulsion valve interface	<ul style="list-style-type: none"> • Cover the expulsion valve with a small rubber diaphragm after releasing the in-socket air over the atmospheric pressure • Add a rubber seal around the housing of the expulsion valve before fabricating the test-socket
Socket-pump interface	<ul style="list-style-type: none"> • Attach an extra rubber seal between the socket and vacuum pump

Figure E.2 shows the in-socket vacuum pressure after managing the air-leakage.

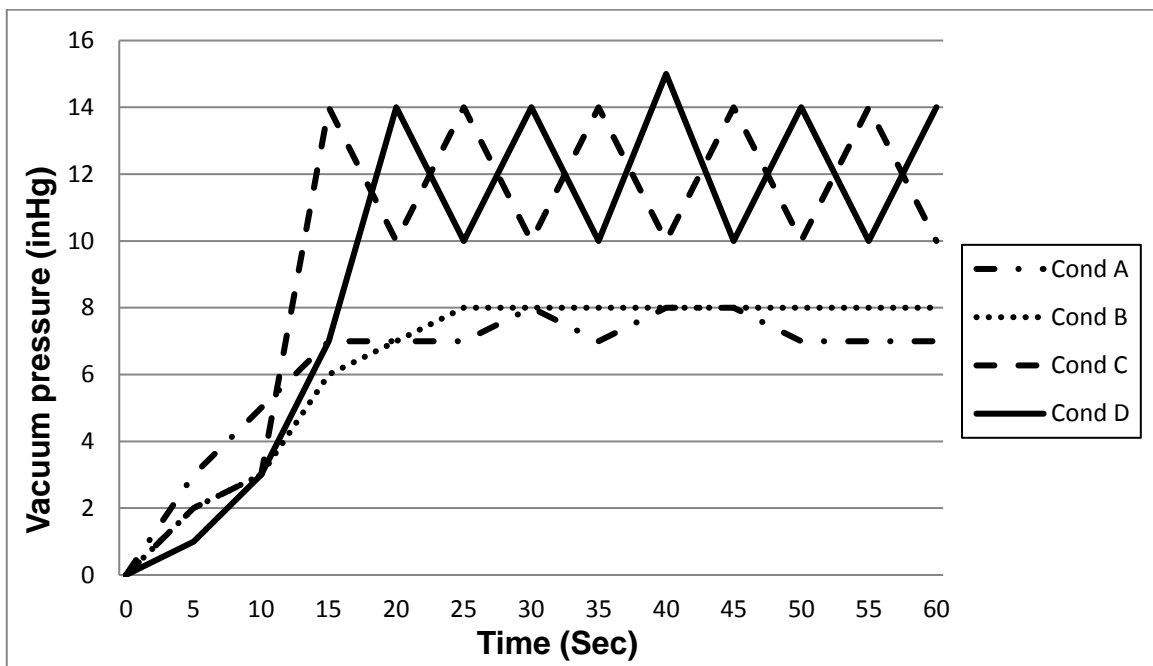


Figure E.2: In-socket vacuum pressure across 4 different conditions, after addressing the different air-leakage locations.

Figure E.2 shows the in-socket vacuum pressure across 4 different conditions, after addressing the different air-leakage locations. The desired vacuum range (10 inHg to 14 inHg) was achieved in conditions C and D, suggesting that the Limb-Logic communicator would work efficiently if the prosthesis sealed properly.

Appendix F: Investigation of the effects of a novel passive socket system on short-term changes in residuum volume, comfort, and gait kinematics and ground reaction forces: A preliminary study in trans-tibial amputees (Chapters 5 and 6)

Appendix F.1: Ethical Approval from the University of Salford



Research, Innovation and Academic
Engagement Ethical Approval Panel

Research Centres Support Team
G0.3 Joule House
University of Salford
M5 4WT

T +44(0)161 295 2280

www.salford.ac.uk/

9 December 2015

Dear Huthaifa,

RE: ETHICS APPLICATION HSCR 15-127 – The effects of in-socket air pressure on short term changes in residuum volume, static pistoning, gait kinematics, and comfort: A comparison between active and passive systems

Based on the information you provided, I am pleased to inform you that application HSCR15-127 has been approved.

If there are any changes to the project and/ or its methodology, please inform the Panel as soon as possible by contacting Health-ResearchEthics@salford.ac.uk

Yours sincerely,



Sue McAndrew
Chair of the Research Ethics Panel

Appendix F.2: Ethical Approval from the NHS



Health Research Authority

Professor Laurence Kenney
PO.43, Brian Blatchford Building
University of Salford
Salford
M6 6PU

Email: hra.approval@nhs.net

24 August 2016

Dear Professor Kenney,

Letter of HRA Approval

Study title:	The effects of in-socket air pressure on short term changes in residuum volume, pistoning, gait kinematics, and comfort: A comparison between active and passive systems
IRAS project ID:	195126
Protocol number:	N/A
REC reference:	16/NI/0151
Sponsor	The University of Salford

I am pleased to confirm that HRA Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Appendix F.3: Participant Invitation Letter



Participant Invitation Letter

Mr. Huthaifa Atallah (postgraduate student)
Centre for Health Sciences Research
School of Health Science
PO.34, Brian Blatchford Building
Frederick Road
University of Salford
Salford, M6 6PU
Mobile: 07769763776
E-mail: h.m.atallah@edu.salford.ac.uk

Dear Sir/Madam

I am writing to invite you to consider participating in a research study at the University of Salford. This study is being carried out to look at a new method for reducing the fluctuations in residuum volume seen by many amputees. Thus, the focus of this project is to find a proper space at the end of the socket that can preserve residuum volume.

For further information about this study and what it will involve; please read carefully the attached (**Participant Information Sheet**). If there is any ambiguity or unclear, or you need further information. Please do not hesitate to contact the researcher, Mr. Huthaifa Atallah, whose details are given both above and at the end of the patient information sheet. Also, you can contact the study supervisor, Dr. John Head, whose details are given in the Participant Information Sheet.

Finally, if you are interested in taking part in the study, please contact the researcher, Mr. Huthaifa Atallah by email, phone, or in person, whose details are given both above and at the end of the patient information sheet. If you decide to participate, the University of Salford will cover your travel expenses and offer you a £50 gift voucher in recognition of your efforts.

Thank you for reading this letter.

Best regards,
Huthaifa Atallah (The researcher)

PIL V 3
26/04/2016

Appendix F.4: Participant Information Sheet

Participant Information Sheet **IRAS Project ID (195126)**

The effects of in-socket air pressure on short term changes in residuum volume, pistoning, gait kinematics, and comfort: A comparison between active and passive systems.

I would like to invite you to take part in a research study at the University of Salford. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. You can ask questions about anything you read is not clear or would like more information. Please take time to decide whether or not to take part.

What is the purpose of the study?

Amputees often experience problems resulting from the change in volume of their residuum over the course of a day. This study is being carried out to look at a new method which may help to reduce the changes in residuum volume seen by many amputees. One factor which research suggests may impact on limb volume changes with time, is the air pressure within the socket. Recently, 2 small scale studies have demonstrated that, by using a vacuum pump attached to the socket to maintain a below-atmosphere socket pressure while walking, limb volume may be better maintained. However, such devices are expensive and require specialist fitting. This study will explore whether, by using a socket with a large void at the distal end, and a one-way pressure relief valve, a passive device may achieve similar benefits, by reducing in-socket pressure fluctuations during gait.

As there is evidence to suggest that using a vacuum pump to maintain a low pressure within the socket can help to maintain residuum volume, we will compare the performance of our new passive socket against both this, and a conventional passive socket. To assess how well our new passive socket works we will measure a number of outcomes, including any changes to your residuum volume after taking the socket off, and the movements of your limbs during walking.

Why have I been invited?

We are interested in studying how to improve the day-day changes in residuum volume in people with trans-tibial amputation. You have been invited to participate in this study as our records suggest you are someone with this level of amputation. Also, you told us that you feel that you experience changes to your residuum volume and/or pistoning while walking with your prosthesis.

Do I have to take part?

It is up to you to decide to take part or not. After reading this information sheet, we will explain the study to you and go through this information sheet. If you are still willing to take part, we will ask you to sign a consent form. However, if you do not wish to take part then you do not have to. You can also withdraw from the study once you have consented at any time, without giving a reason for this.

What will happen to me if I participate in this study?

If you decide to take part, you will be required to come to the School of Health Sciences at the University of Salford for two visits. The first visit will take approximately one hour and will take place in a clinic room in the Brian Blatchford building, University of Salford. During this visit will give you an opportunity to ask questions, before inviting you to sign the consent form. If you consent, you will be invited to take-off your own prosthesis in order for me to take some measurements with a tape measure and a cast of your residuum using Plaster of Paris bandages. These procedures will be similar to those that your prosthetist took when fabricating your prosthesis. Finally, we will invite you to put on your prosthesis.

The second visit will take approximately four hours and will take place in the movement analysis laboratory in the Brian Blatchford building, University of Salford. The activities during this visit are explained below. I will:

1. Invite you to take off your own prosthesis in order to fit you with a test-prosthesis (including a silicon liner) which will have been manufactured based on measurements taken during visit 1. This will require some work to ensure both length and alignment are suitable (60 minutes);
2. Attach reflective markers on your lower limbs (please see *Figure 1*);
3. Rest while wearing the silicone liner only (20 minutes);
4. Measure your residuum volume by using a system you may have seen used by your prosthetist. The system we will use is shown in *Figure 2* below;
5. Wear the test-prosthesis. This will be configured in one of three different ways, reflecting the test-conditions described in *Table 1* (below);
6. Walk with the test-prosthesis a distance of 200 meters approximately in order to allow for any residuum volume changes to occur (5 min);
7. Walk 10 successive trials along pathway 10 m walkway in order to collect your movement data using cameras and in-socket air pressure via the air pressure sensor (10 min);
8. Measure your residuum volume; (as described in step 4);
9. Asking you about how comfortable you were while walking with the test prosthesis (test-condition).
10. Repeat the tasks (from 3 to 9) with different test-condition (please see *Table 1*).

Table 1: Test-conditions

A	Test-socket with small space at the end <u>AND</u> the vacuum pump will be switched OFF
B	Test-socket with large space at the end <u>AND</u> the vacuum pump will be switched OFF
C	Test-socket with small space at the end <u>AND</u> the vacuum pump will be switched ON

Finally, finishing-off (removing the reflective markers and assist you to wear your own prosthesis).



Figure 1: Person with reflective markers attached.



Figure 2: Scanning an amputee's residuum by a hand scanner.

What expenses and payment will be available to me?

In case you need transportation for your visits to the university, the researcher will arrange and pay for a taxi from home and back again. Alternatively, you can make your own transport arrangements, and we will refund any reasonable costs that you incur. In recognition of your efforts, the University of Salford will offer you a £50 gift voucher for participation in the study.

What will I have to do before the testing at Salford?

You will not be asked to make any changes to your lifestyle before the testing at Salford.

What are the possible disadvantages and risks of taking part?

We will be asking you to carry out everyday activities, such as walking. All tests will be carried out using standard measurement equipment. Therefore, we think the risks associated with taking part are very low.

However, if you have upper limb, or bilateral lower limb amputation, an additional safety precaution will be followed. Either myself, or the other person in the lab (testing is always conducted with two researchers present) will walk with you during the walking trials while holding your hand/arm for support. If you feel uncomfortable with this safety procedure, a walking belt would be used as an alternative. This approach would minimise the risk of injury if a fall event occurs and is common practice when testing particularly a weak person.

What are the possible benefits of taking part?

There are no short-term personal benefits to you from participating, but the University of Salford will offer you a £50 gift voucher. However, this study will be very useful in helping us to progress towards finding a better way of managing limb volume changes.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researcher, who will do his best to answer your question,

Researcher's name: Mr. Huthaifa Atallah

Contact number: 07769763776

Email: h.m.atallah@edu.salford.ac.uk

If you do not wish to discuss your complaint with the researcher, you can directly contact the study supervisor,

Supervisor's name: Professor Laurence Kenney

Contact number: 016129 52289

Email: L.P.J.Kenney@salford.ac.uk

Then you can contact the research centres manager at the University of Salford,

Research centres manager's name: Mr. Anish Kurien

Email: a.kurien@salford.ac.uk

Phone: 016129 55276

However, this study is covered under the professional indemnity insurance. Therefore, if you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it.

Will my taking part in this study be kept confidential?

All information which is collected about you during the study will be kept strictly confidential. All data will be collected in the movement laboratory at the University of Salford. Your name and address will be removed from your data, so it cannot be recognised. Finally, all the collected data will be recorded and stored on a secure password-protected University of Salford desktop computer and research team member laptop. These data will not be accessible to anyone other than the research team members. All these data will be disposed of securely after 5 years.

What will happen if I do not carry on with the study?

You are free to withdraw from the study at any time, without giving any reason, and without your legal rights being affected. And all your data will be deleted on the same day.

What will happen to the results of the research study?

The results will be written up in a report that will form part of a doctoral thesis. However, your data will only be included in this report if you sign the Participant Consent Form.

Who is organising and sponsoring the research?

The research is being organised and funded by the Centre of Health Sciences research, University of Salford, Salford, M6 6PU.

Who can be contacted for independent advice about participating in the study?

For independent advice about participating in the study, please contact:

Dr Anita Williams (Post Graduate Research Studies Director)

Phone: 0161 295 7027

E-mail: a.e.williams1@salford.ac.uk

Who can be contacted for further information?

For further information about the study procedures or treatments, or to withdraw from the study, please contact:

Mr Huthaifa Atallah (postgraduate student)

Centre for Health Sciences Research

School of Health Science

PO.34, Brian Blatchford Building

Frederick Road

University of Salford

Salford, M6 6PU

Mobile: 07769763776

E-mail: h.m.atallah@edu.salford.ac.uk

OR

Dr John Head (Lecturer in Prosthetics and Orthotics)

Centre for Health Sciences Research

School of Health Science

PO.47, Brian Blatchford Building

Frederick Road

University of Salford

Salford, M6 6PU

Phone: 01612952303

E-mail: J.Head@salford.ac.uk

Thank you for the time you spent reading this Participant Information Sheet

Appendix F.5: Participant Consent Form

Participant Consent Form **IRAS Project ID (195126)**

Participant number:

Date:

Title of study:

The effects of in-socket air pressure on short term changes in residuum volume, pistoning, gait kinematics, and comfort: A comparison between active and passive systems.

Name of researcher:

Mr. Huthaifa Atallah, postgraduate student, Center for Rehabilitation and Human Performance Research (CRHPR), University of Salford, Salford, M6 6PU.

Please read and initial the following boxes:

1. I confirm that I have read and understood the **Patient Information Sheet** (V 7, 05.08.2016) for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my legal rights being affected. ☐
3. I understand that all my data are secured, and that no one can access my data except research team members. ☐
4. I understand that only my anonymised data will be used in the research. ☐

Name of patient

Date

Signature

Name of person
Taking consent

Date

Signature

(If different from Researcher)

Name of researcher

Date

Signature

One copy for participant and one for investigator file.

Appendix F.6: Poster for participants' invitation

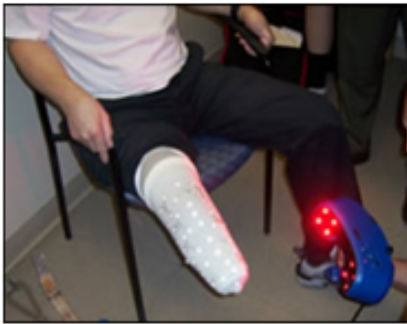


Participants needed for research project
IRAS Project ID (195126)



Are you over 18 years old with unilateral trans-tibial (below-the-knee) amputation and have volume changes in your residual limb and/or pistoning problems?

If so, you are invited to take part in a study to investigate an approach to better managing residual limb volume during walking.




As a participant in this study, you will be asked to attend the Brian Blatchford building at the University of Salford twice.

First visit: For casting and measurements (1 hour)
Second visit: For prosthesis fitting and data collection (4 hours).

You will receive a £50 gift voucher **AND** refund any reasonable costs of transportation.

For more information, please contact

Mr Huthaifa Atallah (PhD Student) 07769763776 h.m.atallah@edu.salford.ac.uk	Mr Huthaifa Atallah (PhD Student) 07769763776 h.m.atallah@edu.salford.ac.uk	Mr Huthaifa Atallah (PhD Student) 07769763776 h.m.atallah@edu.salford.ac.uk	Mr Huthaifa Atallah (PhD Student) 07769763776 h.m.atallah@edu.salford.ac.uk	Mr Huthaifa Atallah (PhD Student) 07769763776 h.m.atallah@edu.salford.ac.uk	Mr Huthaifa Atallah (PhD Student) 07769763776 h.m.atallah@edu.salford.ac.uk	Mr Huthaifa Atallah (PhD Student) 07769763776 h.m.atallah@edu.salford.ac.uk	Mr Huthaifa Atallah (PhD Student) 07769763776 h.m.atallah@edu.salford.ac.uk	Mr Huthaifa Atallah (PhD Student) 07769763776 h.m.atallah@edu.salford.ac.uk	Mr Huthaifa Atallah (PhD Student) 07769763776 h.m.atallah@edu.salford.ac.uk
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V 2
4/1/2017

Appendix G: Randomisation plane for the main study (Chapter 6)

A Randomization Plan from http://www.randomization.com	
1. _____	<ul style="list-style-type: none">◦ Condition C (Active system with small distal void)◦ Condition A (Passive system with small distal void)◦ Condition B (Passive system with large distal void)
2. _____	<ul style="list-style-type: none">◦ Condition B (Passive system with large distal void)◦ Condition A (Passive system with small distal void)◦ Condition C (Active system with small distal void)
3. _____	<ul style="list-style-type: none">◦ Condition C (Active system with small distal void)◦ Condition A (Passive system with small distal void)◦ Condition B (Passive system with large distal void)
4. _____	<ul style="list-style-type: none">◦ Condition A (Passive system with small distal void)◦ Condition B (Passive system with large distal void)◦ Condition C (Active system with small distal void)
5. _____	<ul style="list-style-type: none">◦ Condition B (Passive system with large distal void)◦ Condition C (Active system with small distal void)◦ Condition A (Passive system with small distal void)
6. _____	<ul style="list-style-type: none">◦ Condition B (Passive system with large distal void)◦ Condition A (Passive system with small distal void)◦ Condition C (Active system with small distal void)
7. _____	<ul style="list-style-type: none">◦ Condition C (Active system with small distal void)◦ Condition B (Passive system with large distal void)◦ Condition A (Passive system with small distal void)
8. _____	<ul style="list-style-type: none">◦ Condition A (Passive system with small distal void)◦ Condition B (Passive system with large distal void)◦ Condition C (Active system with small distal void)
9. _____	<ul style="list-style-type: none">◦ Condition A (Passive system with small distal void)◦ Condition C (Active system with small distal void)◦ Condition B (Passive system with large distal void)
10. _____	<ul style="list-style-type: none">◦ Condition A (Passive system with small distal void)◦ Condition C (Active system with small distal void)◦ Condition B (Passive system with large distal void)
10 subjects randomized into 1 block To reproduce this plan, use the seed 9247 Randomization plan created on 7/12/2016, 4:23:09 PM	

Appendix H: Results of statistical analysis (Chapter 6)

Table H.1: Test of normality for RVFs, across the 3 test-conditions.

Tests of Normality							
	Conditions	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
RVFs	A	.207	5	.200*	.945	5	.699
	B	.371	5	.023	.756	5	.034
	C	.315	5	.117	.863	5	.239
*. This is a lower bound of the true significance.							
a. Lilliefors Significance Correction							

Table H.2: Friedman test for RVFs, across the 3 test-conditions.

Test Statistics ^a	
N	5
Chi-Square	7.600
df	2
Asymp. Sig.	.022
Exact Sig.	.024
Point Probability	.015
a. Friedman Test	

Table H.3: Wilcoxon Signed Ranks Test for RVFs, across the 3 test-conditions.

Test Statistics ^a			
	B - A	C - A	C - B
Z	-2.023 ^b	-2.023 ^b	-.405 ^c
Asymp. Sig. (2-tailed)	.043	.043	.686
Exact Sig. (2-tailed)	.063	.063	.813
Exact Sig. (1-tailed)	.031	.031	.406
Point Probability	.031	.031	.094
a. Wilcoxon Signed Ranks Test b. Based on negative ranks. c. Based on positive ranks.			

Table H.4: Test of normality for comfort, across the 3 test-conditions.

Tests of Normality							
	Conditions	Kolmogorov-Smirnov ^a			Shapiro-Wilk		
		Statistic	df	Sig.	Statistic	df	Sig.
Comfort	1.00	.180	5	.200 [*]	.952	5	.754
	2.00	.180	5	.200 [*]	.952	5	.754
	3.00	.243	5	.200 [*]	.894	5	.377
*. This is a lower bound of the true significance. a. Lilliefors Significance Correction							

Table H.5: One-way repeated measures ANOVA test for comfort, across the 3 test-conditions.

Tests of Within-Subjects Effects						
Measure: MEASURE_1						
Source		Type III Sum of Squares	df	Mean Square	F	Sig.
Conditions	Sphericity Assumed	3.733	2	1.867	1.155	.363
	Greenhouse-Geisser	3.733	1.643	2.272	1.155	.359
	Huynh-Feldt	3.733	2.000	1.867	1.155	.363
	Lower-bound	3.733	1.000	3.733	1.155	.343
Error(Conditions)	Sphericity Assumed	12.933	8	1.617		
	Greenhouse-Geisser	12.933	6.572	1.968		
	Huynh-Feldt	12.933	8.000	1.617		
	Lower-bound	12.933	4.000	3.233		

Appendix I: Gait kinematics and Ground Reaction Forces (GRFs) (Chapter 6)

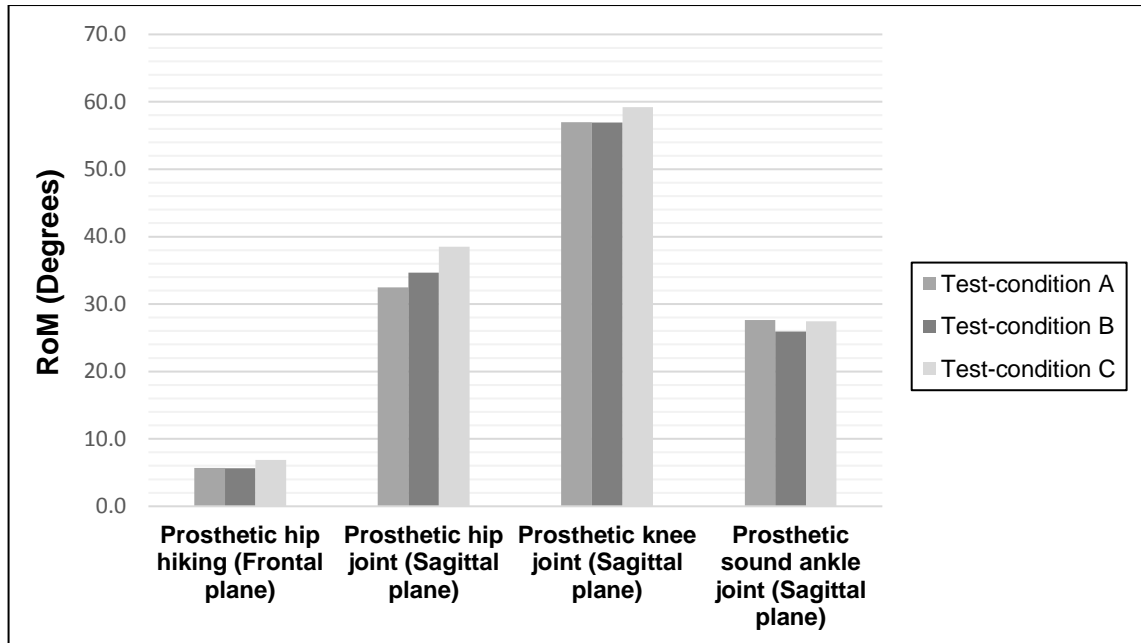


Figure I.1: Joint angle ranges of motion (RoM) for the first participant (Pt1) across the three test-conditions.

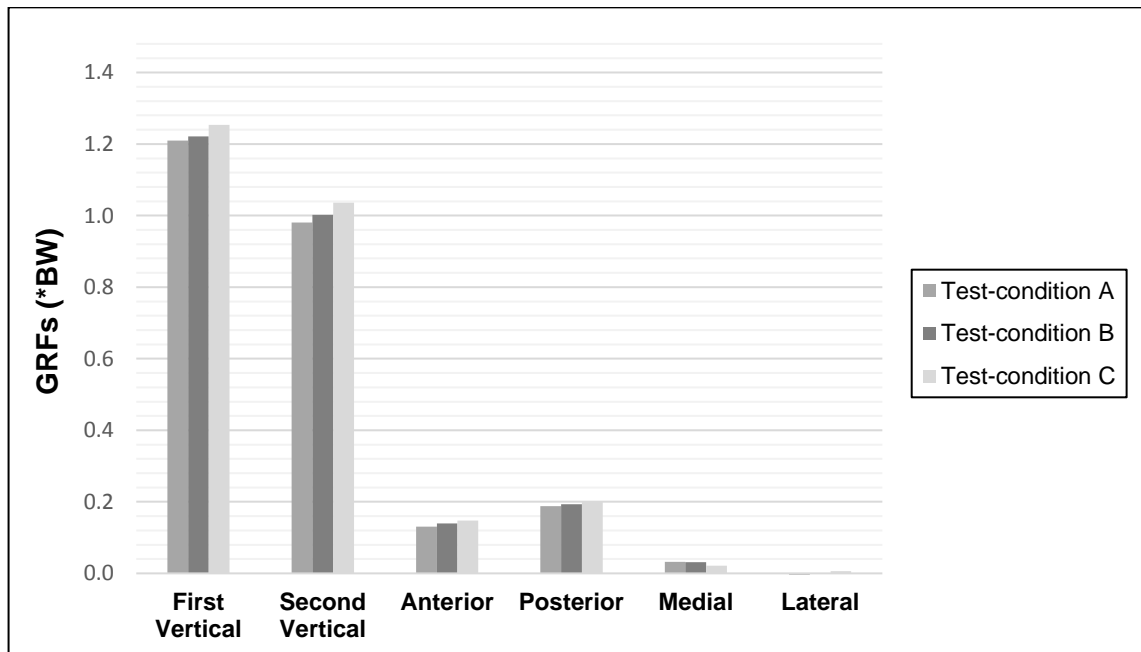


Figure I.2: The peak values of GRFs for the first participant (Pt1) across the three test-conditions.

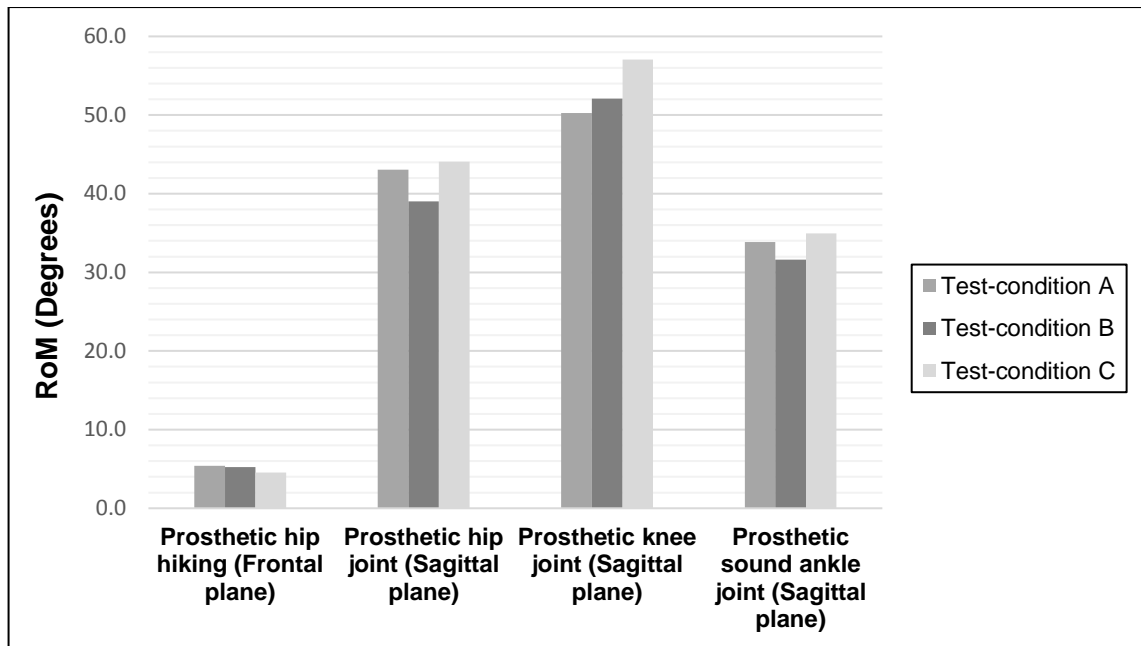


Figure I.3: Joint angle ranges of motion (RoM) for the second participant (Pt2) across the three test-conditions.

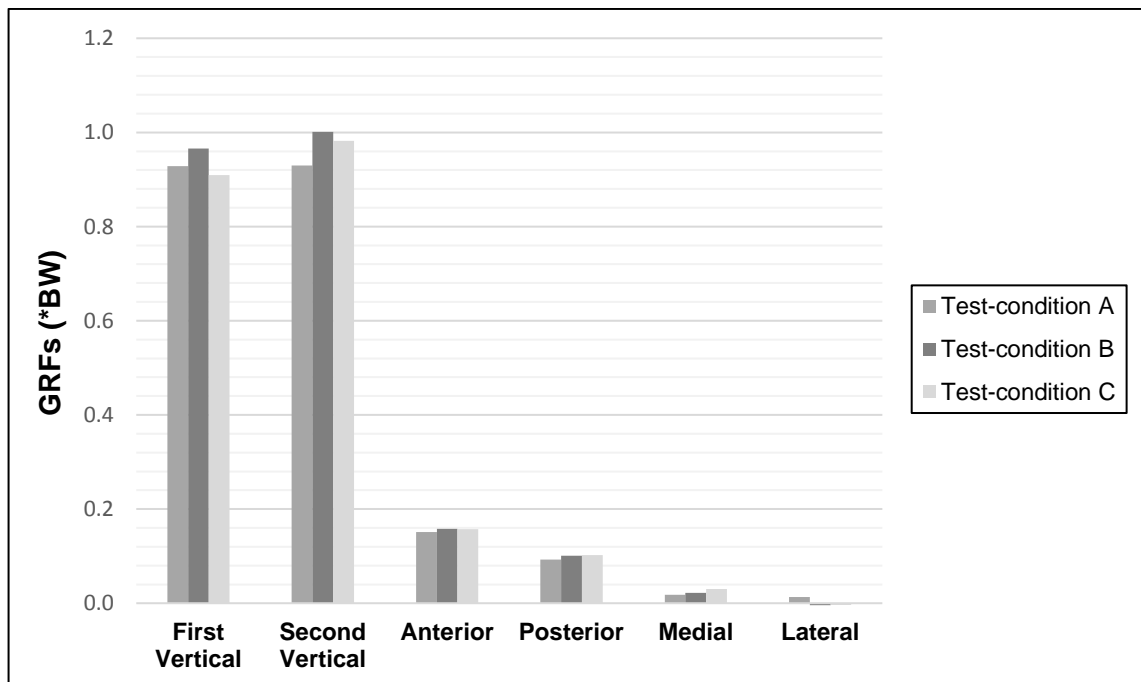


Figure I.4: The peak values of GRFs for the second participant (Pt2) across the three test-conditions.

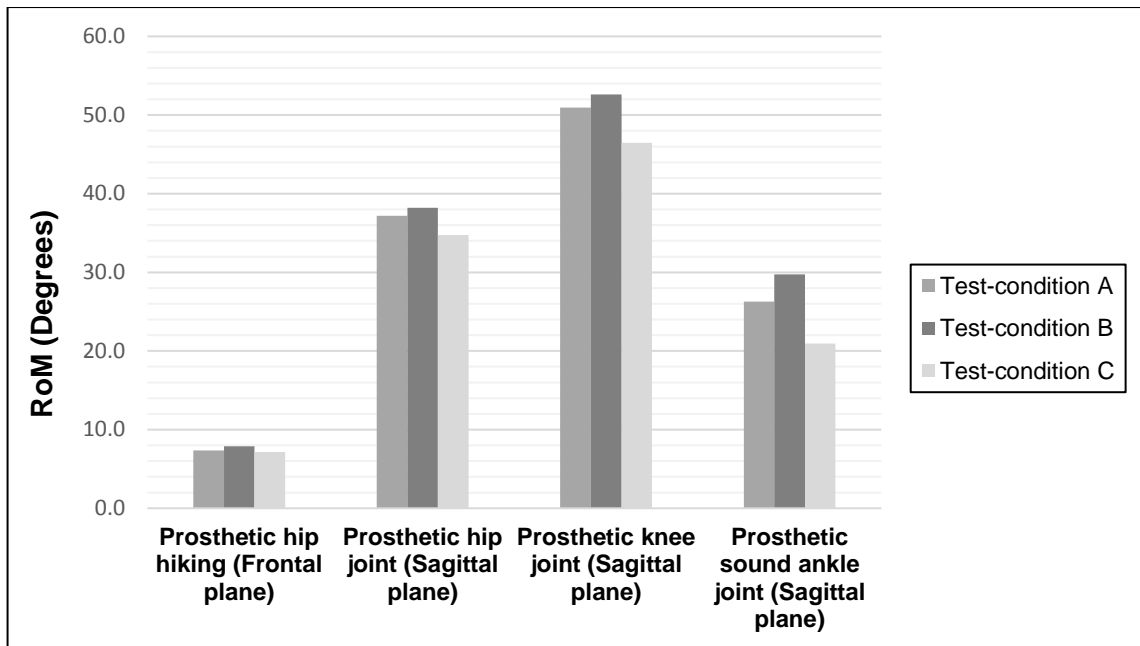


Figure I.5: Joint angle ranges of motion (RoM) for the third participant (Pt3) across the three test-conditions.

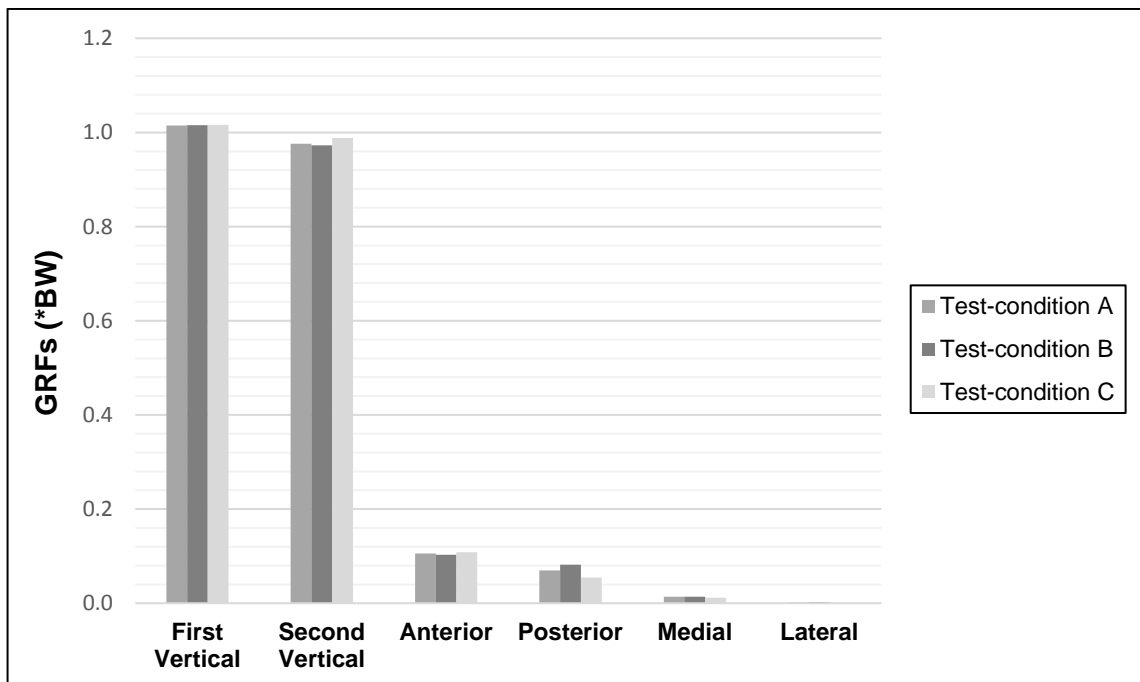


Figure I.6: The peak values of GRFs for the third participant (Pt3) across the three test-conditions.

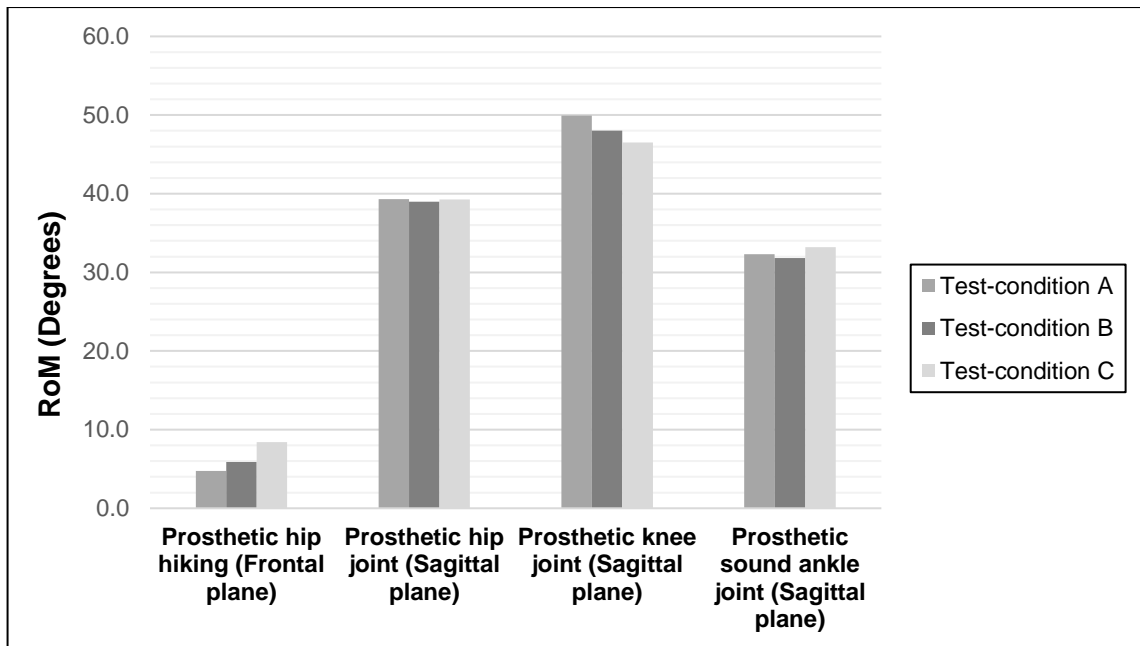


Figure I.7: Joint angle ranges of motion (RoM) for the fourth participant (Pt4) across the three test-conditions.

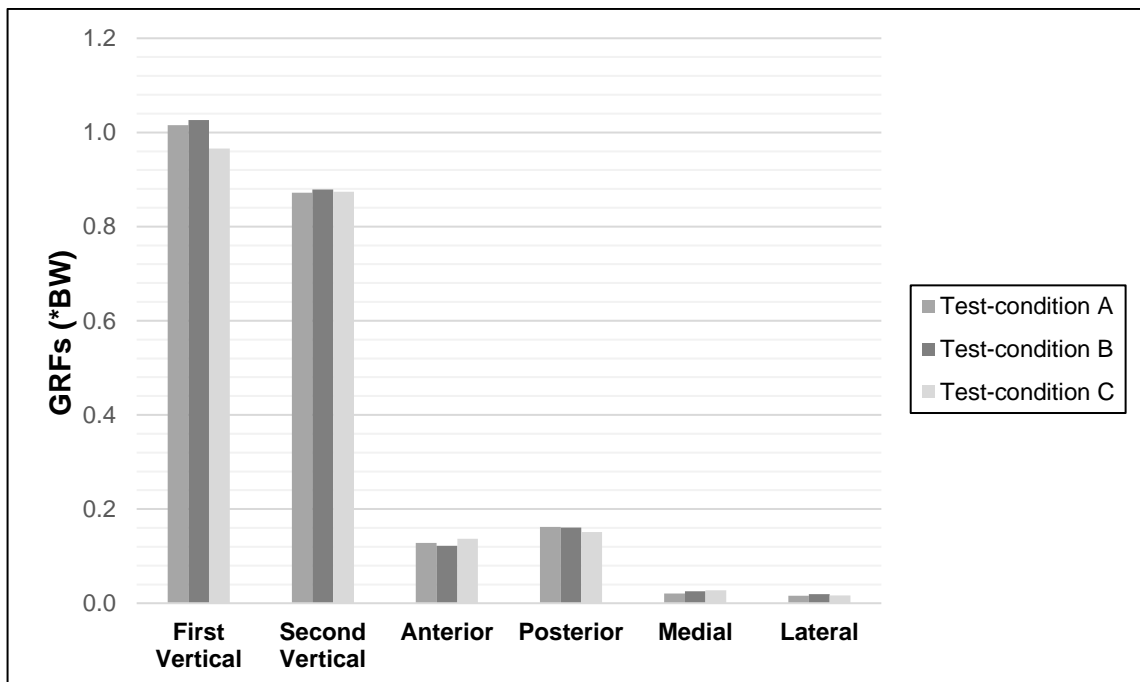


Figure I.8: The peak values of GRFs for the fourth participant (Pt4) across the three test-conditions.

Appendix J: The investigation into obtaining in-socket air pressure profile from the Limb-Logic Communicator

J.1. Aim

The aim of this experiment was to assess the ability to obtain in-socket air pressure profile from the Limb-Logic Communicator during gross oscillations of pressure, designed to simulate the approximate frequency of pistoning during gait.

J.2. Methods

A rubber diaphragm was fitted over the socket and sealed using adhesive tape placed around the outside of the socket (*Figure J.1*). The Limb-Logic Communicator (vacuum pump) was managed through the Limb-Logic software running on a laptop. Screen-capture software was downloaded to record the vacuum readings from the Limb-Logic software during the experiment. Standby mode was selected. A video-camera was set up to film the screen-capture record and trials synchronously.

The gait cycle was mimicked by pushing the plastic diaphragm to the bottom of the socket (to mimic the stance phase) and pull it to the top of the socket (to mimic the swing phase) 7 times over 7 seconds⁶². Pushing and pulling the plastic diaphragm to the maximum was to allow the in-socket air volume and pressure to change significantly. This procedure was repeated 3 times. Finally, the video generated by the camera was replayed to assess the response of the Limb-Logic Communicator during the mimicked gait cycles. The numbers of peaks in the analogue pressure display was recorded.

⁶² The required time for one gait cycle of trans-tibial amputee was considered 1 second approximately.



Figure J.1: The ITTP with a rubber diaphragm. The diaphragm was to pushed into the socket and pulled out every ~1 sec to mimic the gait cycle.

J.3. Results

Table J.1 illustrates how the Limb-Logic Communicator responding to the mimicked swing phases.

Table J.1: Numbers of applied and captured swing phases across 3 trials

Trial	Number of applied simulated swing phases (diaphragm pulled up)	Number of peaks in the Limb-Logic Communicator pressure response
1	7	2
2	7	2
3	7	2

J.4. Discussion

This experiment has demonstrated the response of the Limb-Logic Communicator to the in-socket air pressure changes.

As shown in *Table J.1*, the in-socket vacuum pressure changes were not consistent with the mimicked swing phases. Although the in-socket air volume changed significantly by pushing and pulling the plastic diaphragm to the bottom and the top of the socket 7 times, the Limb-Logic Communicator showed only 2 peaks in its pressure response, suggesting poor dynamic response.

J.5. Conclusions

It not possible to obtain accurate in-socket air pressure profile data during gait using the Limb-Logic Communicator.

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